# Guideline for Sampling in the Commercial-Grade Item Acceptance Process

TR-017218-R1

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# **REPORT SUMMARY**

**The original guideline**, the nineteenth in a series co-sponsored with NCIG, **provided** a methodology for use of sampling in accepting/dedicating commercial-grade items (CGIs). **This revision provides enhanced guidance that should further** improve the effectiveness of sampling decisions from both a technical and a financial standpoint and ensures that item characteristics meet specified requirements.

#### Background

EPRI Report NP-5652, implemented in response to the March 1989 Nuclear Management and Resources Council (NUMARC, now the Nuclear Energy Institute/NEI) Commercial Grade Item Initiative, provided an industry-adopted process for use of CGIs in nuclear safety-related applications. However, the extent of sampling that needed to be performed when verifying critical characteristics remained a recurring question. The EPRI Joint Utility Task Group (JUTG) identified the need for item-specific sampling plans. NCIG agreed that providing a companion guideline (NP-7218) to NP-5652 specifically relating to CGI acceptance sampling would be beneficial to the industry.

In response to the issuance of US Nuclear Regulatory Commission (NRC) Draft Regulatory Guide DG-1070 in October 1997, NEI and EPRI committed to revise the original companion guideline (NP-7218) to address specific sampling issues. NEI described the scope of the guideline revisions in its response to the NRC in January 1998.

#### Objective

• To revise the guideline on the use of sampling plans for CGI acceptance.

#### Approach

A task group of representatives from nuclear power plant licensees and consultants reviewed current industry practices and selected those appropriate for inclusion in **and enhancement to** this guideline. On the basis of this review, **EPRI PSE** developed the guideline **revisions** to provide **additional** information on CGI acceptance sampling for

nuclear power plant licensees, industry organizers, architect/engineers, consultants, and industry suppliers.

#### Results

This guideline **revision** provides a method for using sampling plans in the CGI acceptance/dedication process. **The revision specifically enhances guidance for the following issues:** 

- Sampling sizes for destructive testing
- Considerations of safety function and safety significance when selecting a sample size
- Lot homogeneity considerations
- Documentation requirements

Overall, sampling approaches presented in the guideline integrate qualitative and technical considerations.

#### **EPRI** Perspective

This **revision** provides guidance on sampling specific to the CGI acceptance process. Use of the guideline ensures there is a proper technical justification for sampling plans selected and assists in obtaining industry consistency in sampling approaches. A number of recognized sampling publications are available. However, industry experience has been that they are not directly applicable to CGI acceptance because nuclear plant procurement typically involves small, isolated lots instead of large, production-run populations.

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#### **Interest Categories**

**Plant support engineering** Nuclear plant operations and maintenance Engineering and technical support

#### Keywords

Procurement Quality assurance

# ABSTRACT

This **revised** document provides **enhanced** guidance on the use of sampling plans for CGI acceptance. This guideline was **originally** prepared to address the specific needs of the commercial nuclear industry related to establishing sampling plans as part of the process of accepting CGIs. **The revision specifically enhances guidance for the following issues:** 

- Sampling sizes for destructive testing
- Considerations of safety function and safety significance when selecting a sample size
- Lot homogeneity considerations
- Documentation requirements

The sampling approaches presented in the guideline integrate qualitative considerations with a reasonable technical approach. A process for CGI acceptance sampling is provided, which includes important steps such as lot formation and the selection of the sampling plans. Three recommended sets of nondestructive test and inspection sampling plans are included. **Detailed guidance** is also provided on the selection of sample sizes when destructive tests and inspections are required. Examples illustrate the proper use of the guideline methodology.

The material in this guideline does not add requirements to those in existing codes, standards, and regulations. The guidance herein is intended to complement existing information and practices. This guideline is intended to be used in conjunction with the companion EPRI/NCIG document, EPRI NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*, and EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items.

### ACKNOWLEDGMENTS

**During the development of the original guideline** the following individuals were ongoing members of NCIG's Sampling Plan Task Group. As such, they have made significant contributions to the development of this guide by attending the majority of the task group meetings, reviewing and commenting on various drafts, and writing portions of the document.

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# **1** INTRODUCTION

#### 1.1 Format for Revisions

For the purposes of this revision, all text that has either been added or revised from the original report is shown in bold font. Text that is shown in normal font represents the original, as-published guidance.

#### 1.2 Background

EPRI Report NP-5652, implemented in response to the March 1989 Nuclear Management and Resources Council (NUMARC, now the Nuclear Energy Institute/NEI) Commercial Grade Item Initiative, provided an industry-adopted process for use of CGIs in nuclear safety-related applications. However, the extent of sampling that needed to be performed when verifying critical characteristics remained a recurring question. The EPRI Joint Utility Task Group (JUTG) identified the need for item-specific sampling plans. NCIG agreed that providing a companion guideline (NP-7218) to NP-5652 specifically relating to CGI acceptance sampling would be beneficial to the industry.

In response to the issuance of US Nuclear Regulatory Commission (NRC) Draft Regulatory Guide DG-1070 in October 1997, NEI and EPRI committed to revise the original companion guideline (NP-7218) to address specific sampling issues. NEI described the scope of the guideline revisions in its response to the NRC in January 1998.

This guideline **revision still** provides a methodology for the use of sampling in the process of accepting/dedicating commercial-grade items (CGIs) for nuclear safety-related applications. **The revisions enhance guidance to address the following issues:** 

- Sampling sizes for destructive testing
- Considerations of safety function and safety significance when selecting a sample size
- Lot homogeneity considerations
- Documentation Requirements

In order to assure the continued safe and reliable operation of nuclear power plants, utilities need to have confidence that items used in their plants will perform their intended functions. The acceptance/dedication of items to be used in safety-related applications is essentially the final step in the overall procurement process of obtaining and receiving CGIs for these applications.

The steps preceding this acceptance/dedication are treated in previous EPRI/NCIG guidelines. These guidelines include:

- Safety Classification of Systems, Components, and Parts Used in Nuclear Power Plant Applications, NP-6895 and NCIG-17
- Technical Evaluation of Replacement Items in Nuclear Power Plants, NP-6406 and NCIG-ll
- Preparing Specifications for Nuclear Power Plants, NP-5638 and NCIG-04
- Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications, NP-5652 and NCIG-07
- Procurement and Receipt of Items for Nuclear Power Plants, NP-6629 and NCIG-15
- Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items, TR-102260

Sampling techniques used in the acceptance/dedication process can provide reasonable assurance that characteristics of an item meet specified requirements.

#### 1.3 Applicability of Sampling to Commercial-Grade Item (CGI) Acceptance

Figure 1-1 is an expansion of the Figure 1-1 that appears in EPRI Report NP-5652 [14]. It illustrates that the combination of the technical evaluation and the acceptance process provides assurance that the CGI will meet the dedication requirements of 10 CFR 21 [13,14]. When sampling is required as a part of the acceptance process, the selection of the appropriate sampling plan complements the critical characteristic selection process in providing reasonable assurance of CGI conformance. Because of numerous procurement qualitative factors, it is normally not necessary to perform 100 percent (%) tests and/or inspections to obtain reasonable assurance of item conformance to acceptance requirements.



Figure 1-1 Utilization of Commercial-Grade Items

Procurements for nuclear power plants generally involve quantities that are small relative to the large production lots that are addressed in most of the well-recognized sampling plans. Therefore, sampling plans that specifically address the acceptance of small lots of CGIs will be addressed in this guideline.

The sampling approaches presented in **Chapter 2** provide tools to aid in providing reasonable assurance that selected critical characteristics conform to acceptance requirements. The sampling approaches integrate qualitative considerations with a reasonable technical approach. References on acceptance sampling recognize that effective sampling programs need to consider qualitative factors, such as supplier product acceptance history, and not just pure statistics [8,15]. Evaluation of these qualitative factors using technical judgment determines the need for more or less assurance from a sampling standpoint.

An additional basis for the sampling approaches and plans in **Chapter** 2 is that the acceptance sampling process is only one part of the procurement program to assure that a CGI can perform its intended safety-related function. Up-front activities can include:

- A technical evaluation to assure that the proper item is being specified in the procurement document.
- A screening of potential suppliers to assure that only reputable ones are being used.

- Clearly specifying in procurement documents the technical and quality requirements applicable to an item.
- An assessment of the product manufacturer's production controls and quality checks.

After a lot is accepted using the sampling process, certain plant practices under the utility's 10 CFR 50, Appendix B program that further assure the acceptability of an item can include:

- Maintenance personnel comparing the old item versus the new item at the time of installation
- Standard post-installation tests and inspections
- Periodic maintenance checks, surveillances, and equipment testing

In summary, all of these activities provide assurance that the installed item is acceptable for its safety-related application.

Figure 1-2 illustrates that for the same CGI different sampling plans may can be appropriate for the same CGI. The sampling plans selected for Critical Characteristics 1, 2, and 3 might differ. There are a variety of reasons why the plans can be different. In each case, however, the sampling plan selected provides reasonable assurance that the critical characteristic meets the established acceptance criteria. If the results of the verifications are acceptable, then there is reasonable assurance that the CGI received meets the specified acceptance requirements. For a given CGI, it is possible to achieve reasonable assurance with different combinations of selected critical characteristics and sampling plans.



\* For each critical characteristic, a different sampling plan may be selected based on a number of different factors. The objective of each plan is to provide reasonable assurance the above respective critical characteristics are conforming.

#### Figure 1-2 Sampling Plans and Reasonable Assurance

This guideline provides attributes sampling plans. Variables sampling plans, although an acceptable method of sampling, are not provided in this guideline. Military Standard (MIL-STD) 414 variables sampling plans are briefly discussed in Appendix A, which provides a brief discussion of alternate types of sampling methodologies [20].

Although this guideline was specifically developed for the acceptance/dedication of CGIs for safety-related applications, this guideline can be used in other applications.

#### 1.4 Basic Premises of the Guideline

#### 1.4.1 Engineering Judgment

The selection of critical characteristics for acceptance from the CGI's critical characteristics for design is a decision based on engineering judgment. This same concept is extended to the selection of sampling plans for critical characteristic

verification. Sound engineering judgment in the selection of the appropriate sampling plans is the key to obtaining the necessary reasonable assurance.

#### 1.4.2 Manufacturers' Product Controls

The utility acceptance program consists of verifications of selected critical characteristics to obtain reasonable assurance that the supplier provided an item that meets the acceptance requirements. For various reasons, most commercial manufacturers establish controls and checks to assure that the product meets the manufacturer's specified requirements. These controls can include quality assurance programs, quality control programs, statistical process control programs, tests, and inspections. These are the first line controls that are used to assure the item supplied conforms to the purchaser's acceptance requirements. Objective evidence of the supplier's ability to provide acceptable items is a key factor in determining which guideline sampling approach should be used.

#### 1.4.3 Random Sample Selection

This guideline assumes that samples will be drawn from a lot on a random basis. The random sample selection should be accomplished in such a manner that each item in the lot to be verified has an equal opportunity of being selected as part of the sample. Many publications provide guidance on random sample selection, including: "Basic Random Sampling," *Sampling Techniques, Statistical Quality Control, Quality Control Handbook*, and *Elementary Survey Sampling* [6, 7, 11, 16, 24].

#### 1.4.4 Acceptance of Lot

If the sample results are acceptable, then there is reasonable assurance that the remainder of the lot is acceptable. As with any acceptance sampling plan, it is possible an accepted lot might contain defectives. Post-acceptance controls required by a nuclear power plant's quality assurance program, however, help to assure defective items are discovered before causing an operational concern. When defectives are discovered in the sample, the lot might be ultimately accepted. Section 2.5.3 discusses ways this acceptance can occur.

#### 1.4.5 Documentation

The commercial grade item acceptance sampling process and the bases for sampling plan selection and application should be adequately documented. Documentation should address such factors as lot formation, complexity of the item, adequacy of supplier control as appropriate, safety function, test methodology, product performance, acceptance history of a supplier, item performance history, and other qualitative factors. This guideline is not intended to define the format or details of the documentation requirements. Documentation may be generic in nature or specific to a given circumstance.

# **2** SAMPLING METHODOLOGY FOR COMMERCIAL-GRADE ITEM ACCEPTANCE

#### 2.1 Acceptance Sampling Process

Figure 2-1 illustrates the process for CGI acceptance sampling. The first two steps of the process are discussed in EPRI Report NP-5652. These steps are:

- 1. Selection of the CGI's critical characteristics for acceptance.
- 2. Selection of the acceptance method(s) to verify each critical characteristic for acceptance.

The relationship between the acceptance methods and sampling approaches is discussed in Section 2.2 of this guideline.

The remaining four steps in the sampling process are:

- 3. Formation of the lot to be sampled.
- 4. Selection of the appropriate sampling plan for each critical characteristic to be verified.
- 5. Implementation of the sampling plans.
- 6. Documentation of the results and acceptance trending.

The sampling process is primarily intended for use with CGI Acceptance Method 1, Special Tests and Inspections (hereafter, Acceptance Method 1), or Acceptance Method 3, Source Verification (hereafter, Acceptance Method 3). Section 2.2 provides further explanation.



Figure 2-1 Process for Commercial-Grade Item Acceptance Sampling

#### 2.2 Acceptance Methods and Sampling Plan Approaches

The applicability of the sampling plans presented in this guideline will vary depending on the acceptance method chosen. The four acceptance methods presented in EPRI Report NP-5652 are:

- Method 1, Special Tests and Inspections
- Method 2, Commercial-Grade Survey of Supplier
- Method 3, Source Verification
- Method 4, Acceptable Supplier/Item Performance Record

Figure 2-2 illustrates the relationship between the acceptance methods and the sampling approaches presented in **Chapter** 2. Suggested sampling approaches for each acceptance method follow.



\* The sampling plans in Section 2.4 are not intended for programmatic investigations.

#### Figure 2-2 Relationship Between Acceptance Methods and Sampling Plan Approaches

#### Method 1, Special Tests and Inspections

The sampling plans and guidance in Section 2.4 are most useful when special tests and inspections are utilized to accept an item.

#### Method 2, Commercial-Grade Survey of Supplier

The sampling plans in Section 2.4 are normally not applicable to commercial-grade surveys. However, once a commercial-grade survey is being utilized to accept CGIs, the accepting party can conduct periodic product overchecks, particularly during extended periods between surveys, to assure that no negative changes are occurring in the acceptability of the product. Product overchecks (see Section 2.7) provide additional

assurance that the supplier is continuing to exercise the controls observed during the survey. This is a discretionary practice.

#### Method 3, Source Verification

The sampling plans in Section 2.4 might be appropriate when source verifications are used to accept CGIs. The plans can be used to establish the number of verification tests and inspections to witness at a supplier's facility. Because the source verification allows the direct observation of supplier controls, a reduced sample size might be justified as opposed to when using Method 1. Rule-of-Thumb plans described in Appendix A are often used for source verifications.

Source verifications can also involve selective programmatic reviews of the supplier's controls (for example, design control or procurement) for the particular CGI being purchased. The sampling plans in Section 2.4 are not intended to be used for these programmatic investigations.

#### Method 4, Acceptable Supplier/Item Performance Record

The primary use of sampling for Method 4 would be performing product overchecks. Once an acceptable supplier/item performance record is established, product overchecks could be used to assure that no negative changes are occurring in the acceptability of the product.

#### 2.3 Lot Formation

The establishment of the lot to be sampled is an important consideration when selecting the appropriate **sample** plan. The confidence in the homogeneity of the lot is directly related to how the lot is formed. Lot homogeneity is typically a matter of degree and not an absolute. If a lot were truly homogenous, all attributes and variables for every item in the lot would be identical. In that case, only one item would have to be sampled to be representative of the lot.

The reason sampling plans can be used when the ideal of production traceability does not exist stem from the statistical structure of sampling plans. Attribute sampling plans recognize that certain items in the lot may conform to the acceptance criteria (acceptable items) while other items may not conform to the acceptance criteria (defective items). Using this concept, operating characteristic (OC) curves provide a plot of the probability of acceptance versus the quality of submitted lots. The quality of submitted lots is defined as the percentage of nonconforming items in a received lot. For example, using a certain sampling plan its OC curve could indicate the probability of accepting a lot if it contained ten percent defectives. The OC curves in turn are used to make a subjective decision as to the degree of risk that exists using a given sampling plan.

The curve is determined purely by a probability calculation based on:

- Sample size
- Accept/reject numbers
- Lot size (in certain situations)
- Percent defective in the received lot

Homogeneity is not a factor in making this calculation. Therefore, acceptance sampling plans can be used regardless of the degree of lot homogeneity. Homogeneity is a factor however, in determining the degree of sampling necessary.

When a purchase order line item is presented for acceptance, there is reason to assume a certain level of homogeneity. The line item is made up of like type items, specified with the same technical and quality requirements, and expected to meet invoked acceptance criteria. Additional confidence in the homogeneity of the lot is directly related to how the lot is formed. Lot formation is typically established in one of the following ways:

<u>Production</u> <u>Traceability</u>	These lots provide specific traceability to a product manufacturer's heat number, production lot number, or	
	batch number. Items within this lot can be supplied to the	
	distributor that has maintained production traceability.	
Line Item/Single	These lots are traceable to a specific purchase	
Product Manufacturer	order line item, and the products are from a single product manufacturer. These lots can be supplied to the purchaser	
	by the manufacturer or by a distributor that has maintained product manufacturer traceability.	
Line Item/Multiple	These lots are traceable to a specific purchase order line	
Product Manufacturers	item, but either different product manufacturers might	
	have produced the items in the lot or product manufacturer traceability does not exist.	

For a given lot size, if Production Traceability exists, a high degree of lot homogeneity would be expected. If a non-conforming characteristic is present, a large percentage of items in the lot would probably possess this non-conforming characteristic. Therefore, a relatively small sample size would be needed to detect

this non-conforming characteristic. If only Line Item/Multiple Product Manufacturers traceability exists, there would be reduced confidence in lot homogeneity. In this case, a larger sample size would be selected to give greater confidence the sample results are representative of lot quality. In both cases however, Figure 2-3 illustrates how the technical person selecting the sampling plans has the same level of reasonable assurance a correct disposition of the lot will be made based on the sample results.

Reasonable assurance a correct lot disposition





**Figure 2-4** illustrates the factors that should be considered when forming the lot to be sampled. Appendix B **of this report** provides examples of how the different ways to form the lot influence the sampling approach selected.



Figure 2-4 Lot Formation Factors

#### 2.4 Selection of Sampling Plans

#### 2.4.1 Sampling Plan Categories

This guideline provides sampling approaches for two categories of tests and inspections. The categories are:

- Nondestructive
- Destructive

The sampling plans provided in Section 2.4.3 are for cases when a verification test or inspection is considered nondestructive because it does not adversely affect the design function of the sampled item. The sampling approach provided in Section 2.4.4 for

those cases where a test or inspection is considered destructive because it can adversely affect the design function of the sampled item.

In isolated cases, a test may be nondestructive in certain situations and destructive in others. An example is hardness testing. For some CGIs, a hardness test indentation can be a sufficient stress riser to potentially cause a premature failure of the item. For other CGIs, the hardness test indentation, if taken in the proper locations, will have no effect on the usability of the sample.

Another example of a destructive hardness test is when coating must be removed from a fastener to obtain accurate hardness results.

#### 2.4.2 Sampling Plan Selection Factors

In addition to providing a sampling methodology, this guideline provides a recommended set of three nondestructive sampling plans and a sampling approach when destructive tests and inspections are required. Other options include performing 100% verification or developing an alternate sampling plan. Thus, the guideline allows sampling selection flexibility based on a technical review of different factors.

Sampling plan selection factors for a given critical characteristic include the following:

- Product/Supplier Factors
  - Acceptance history of supplier's products
  - Formed lot (indication of degree of homogeneity)
  - Item performance history
  - Complexity of the item
  - Applicability of industry standards to the item
  - Supplier controls
  - Safety significance of the item
- Testing or Inspection Factors
  - Acceptance method chosen
  - Whether verification technique is nondestructive or destructive
  - Number of other critical characteristics being verified

- Cost-effectiveness of the test or inspection
- Correlation between nondestructive and destructive tests

**Figure 2-5** illustrates selection factors that should be considered when selecting the appropriate sampling plan for a given critical characteristic. The selection factors provide qualitative input used by engineering in determining the appropriate sampling plan. Utilizing engineering judgment, a sampling plan should be selected that provides sufficient confidence in the sample results considering the relevant selection factors. Sections 2.4.3 and 2.4.4 discuss the decision process for nondestructive and destructive tests and inspections, respectively.



\*Additional selection factors to consider for destructive tests and inspections

#### Figure 2-5

Sampling Plan Selection Factors for a Specific Critical Characteristic

**Chapter** 3 provides six application examples that illustrate how selection factors would be used to arrive at a sampling plan decision for each selected critical characteristic.

#### 2.4.3 Sampling Plans for Nondestructive Tests and Inspections

A recommended set of sampling plans has been developed for nondestructive tests and inspections. Normal, Reduced, and Tightened Sampling Plans are contained in Table 2-1. The Normal Sampling Plan should be considered first. When less discrimination is considered justified, then the Reduced Sampling Plan might be appropriate. When more discrimination is considered warranted, the Tightened Sampling Plan might be appropriate.

Norn	nal plan	Reduc	ed plan	Tighter	ned plan
Lot size	Sample size	Lot size	Sample size	Lot size	Sample size
1	1	1-5	1	1	1
2-4	2	6-13	2	2	2
5-6	3	14-24	3	3-4	3
7-11	4	25-41	4	5-6	4
12-20	5	42-50	5	7-8	5
21-24	6	51-63	6	9-10	6
25-28	7	64-76	7	11	7
29-32	8	77-90	8	12-13	8
33-41	9	91-102	9	14-15	9
42-50	10	103-114	10	16-20	10
51-56	11	115-126	11	21-25	11
57-62	12	127-138	12	26-31	12
63-69	13	139-150	13	32-38	13
70-76	14	151-175	14	39-46	14
77-83	15	176-200	15	47-50	15
84-90	16	201-225	16	51-54	16
91-96	17	>225	16	55-58	17
97-102	18			59-62	18
103-108	19	Tightened	l plan con't	63-66	19
109-114	20	Lot size	Sample size	67-70	20
115-120	21	127-130	35	71-74	21
121-126	22	131-135	36	75-78	22
127-132	23	136-140	37	79-82	23
133-138	24	141-145	38	83-86	24
139-144	25	146-150	39	87-90	25
145-150	26	151-158	40	91-94	26
151-162	27	159-166	41	95-98	27
163-174	28	167-174	42	99-102	28
175-186	29	175-182	43	103-106	29
187-198	30	183-190	44	107-110	30
199-210	31	191-198	45	111-114	31
211-225	32	199-207	46	115-118	32
>225	32	208-216	47	119-122	33
		217-225	48	123-126	34
		>225	49	Con't in ce	nter column

# Table 2-1Recommended Set of Nondestructive Test and Inspection Sampling Plan

(For all plans: accept on 0 defects; reject on 1 or more defects.)

The selection factors listed in Section 2.4.2 should be considered when selecting the appropriate sampling plan. The three plans provide the flexibility to chose the appropriate sampling plan for a given critical characteristic. After a review of the selection factors, sound engineering judgment is used to select a plan. The evaluator selects the appropriate sampling plan based on the additional level of confidence (that is, average, low, or high) considered necessary. For a given CGI requiring acceptance, different sampling plans can be selected for different critical characteristics.

#### 2.4.3.1 Normal Sampling Plan

The Normal Sampling Plan should be initially considered when selecting a sampling plan for nondestructive tests and inspections. Factors that might justify engineering selecting the Normal Sampling Plan can include:

- The expectation that the lot will be acceptable based upon available knowledge of the product manufacturer or supplier.
- The lot is expected to have a sufficient homogeneity that a randomly selected sample will represent the whole.

#### 2.4.3.2 Reduced Sampling Plan

The Reduced Sampling Plan should be considered when less discrimination is considered necessary to assure critical characteristic conformance. Some of the factors that can justify engineering selecting the Reduced Sampling Plan include:

- Acceptance trending provides objective evidence that the product manufacturer or distributor has consistently had a satisfactory product acceptance history.
- The lot formation is based on a product manufacturer's heat number, production lot number, or batch number.
- The multiple critical characteristics are being verified on items in the formed lot from a single product manufacturer. Once these multiple critical characteristics are found conforming, the Reduced Sampling Plan can be considered for the remaining critical characteristic because it is reasonable to assume that the product manufacturer has exercised similar satisfactory controls over this characteristic.
- A satisfactory item performance history exists.
- The item is a standardized product manufactured to a national standard.
- The cost-effectiveness of the test/inspection is low.

- The item is simple.
- The critical characteristic has a low safety significance

#### 2.4.3.3 Tightened Sampling Plan

The Tightened Sampling Plan should be considered when more discrimination is considered warranted to assure critical characteristic conformance. Some of the factors that can justify engineering selecting the Tightened Sampling Plan can include:

- Based upon available information on the product manufacturer, distributor, or item, there is concern that the lot is nonconforming.
- The lot consists of like-items from multiple or unknown product manufacturers.
- The homogeneity of the lot needs to be assessed to justify small sample sizes for other critical characteristics.
- The item is not produced to a national standard.
- The cost-effectiveness of the inspection/test is high.
- The item is a complex assembly.
- The item has a high safety significance
- 2.4.3.4 Recommended Set of Nondestructive Test and Inspection Sampling Plan Tables

Table 2-1 provides the recommended set of nondestructive test and inspection sampling plan tables. The statistical basis for the sampling plans presented is contained in Appendix C of this guideline.

For all three sampling plans, if a critical characteristic of a sampled item does not meet the established acceptance criteria, the sampled item is classified as a defective. The lot acceptance basis is to accept the lot if the sample has no defectives and to reject the lot if the sample has one or more defectives.

#### 2.4.4 Sample Size Selection for Destructive Tests and Inspections

When destructive testing or inspection is required to verify a critical characteristic, utilizing the sample sizes specified in Table 2-1 is not practical. The need for smaller sample sizes when destructive testing is involved has been recognized for material testing [2, 3, and 4] and equipment qualification testing. For commercial grade

acceptance, prudent up-front planning to obtain the optimum lot formation available and consideration of the interrelationship between critical characteristics can justify the use of small sample sizes when destructive test or inspections are specified in the acceptance plan. The following three options should be considered based on the type of traceability the supplier can furnish.

#### 2.4.4.1 Option 1 (When Production Traceability Exists)

When destructive testing or inspection is required, the first step should be to determine if the item can be ordered with production traceability. If the lot to be sampled is all from the same heat number, production lot number, or batch number, then there is a high level of confidence that the items within the lot will have similar properties. Therefore, when production traceability exists, a sample size of one is normally sufficient.

# 2.4.4.2 Option 2 (When Line Item/Single Product Manufacturer Traceability Exists)

If the item cannot be obtained with production traceability, then the next step should be to determine if the item can be obtained with a Line Item/Single Product Manufacturer lot formation. With this type of lot formation, the sample size should change based on lot size. Table 2-2 provides a recommended destructive test sampling plan table for Line Item/Single Product Manufacturer lot formations.

Table 2-2

Recommended Destructive Test and Inspection Sampling Plan for Line Item/Single Product Manufacturer Lot Formations

Lot Size	Sample Size
1 -10	1
11 -30	2
31 - 70	3
71 - 150	4
151 - 310	5
311 - 630	6
631 - 1270	7
1271 - 2550	8
> 2551	9

BASIS: This sampling plan for destructive testing and inspection is similar to Table 1 in ASTM F302 except a combination of arithmetic/geometric progressions is used which results in incremental increases in sample size for each doubling in lot range.

#### 2.4.4.3 Option 3 (When Line Item/Multiple Product Manufacturers Traceability Exists)

The third type of lot formation, Line Item/Multiple Product Manufacturers, should be avoided whenever destructive testing is required. With this type of lot formation, there is the lowest confidence in lot homogeneity. Typically up-front planning and specifying lot formation requirements in the purchase order will prevent encountering this type of lot formation. If this type of lot formation must be used, the Table 2-1 reduced sampling plan is recommended for destructive testing.

In addition to lot formation considerations, the following factors can also provide justification for small destructive test and inspection sample sizes:

- The successful verification of other non-destructive critical characteristics at larger sample sizes provides additional confidence in the destructive test or inspection results since the satisfactory results demonstrate effective supplier quality controls.
- The existence of a correlation between a non-destructive test and destructive test. For example, hardness has a direct correlation with tensile strength for many material types. An increased sample size for the non-destructive hardness test can compensate for the small sample size chosen for the tensile strength test.
- The supplier has a history of providing a consistently conforming product.
- A satisfactory item performance history often provides evidence that the supplier has been providing items meeting the destructive test or inspection acceptance criteria.
- Destructively testing or inspecting multiple samples the first time a supplier's commercial grade item is accepted can justify small sample sizes on subsequent orders because of the confidence obtained if the results are acceptable. This is a supplier qualification technique.
- The item is produced to a national standard that specifies the critical characteristics' acceptance requirements.
- The cost-effectiveness of the test/inspection is low.

#### 2.5 Sampling Plan Implementation

#### 2.5.1 Destructive Test Sample Considerations

When destructive testing is required, special consideration should be given to the number and types of test samples needed. Based on the number of test samples needed, the order quantity should be adjusted.

The type of test specimen required should be investigated prior to issuing the purchase order. In certain cases, the item cannot be tested in its final form. In some cases, a special test specimen might be required (for example, for mechanical property tests or durometer hardness tests). The purchase order should require heat number, production lot number, or batch number traceability between the test specimen and the submitted lot.

#### 2.5.2 Selection of Items to be Sampled

Once the critical characteristics to be verified have been identified and the sample size for each critical characteristic has been chosen, there are different approaches for selecting samples to verify the critical characteristics. In Approach A, the same samples are used to verify all the critical characteristics. In Approach B, a different sample is taken from the lot to verify each critical characteristic.

For example, a lot of 30 items is received. Critical Characteristics A, B, and C must be verified. For illustration purposes, each item in the lot is assigned a unique number, and the selected sample size is the same for each critical characteristic. The sampling approach would be as follows for each case:

Critical Characteristic	Sample Size	Identification Numbers of the Items
А	8	1, 5, 10, 14, 18, 20, 28, 29
В	8	1, 5, 10, 14, 18, 20, 28, 29
С	8	1, 5, 10, 14, 18, 20, 28, 29

#### Approach A

#### Approach B

Critical Characteristic	Sample Size	Identification Numbers of the Items
A	8	15, 25, 29, 14, 18, 28, 10, 3
В	8	16, 7, 19, 1, 20, 21, 13, 5
С	8	9, 11, 2, 4, 12, 30, 8, 17

For Approach B, the objective is to verify a critical characteristic on as many items in the lot as possible.

In Approach A, three critical characteristics would be verified on 27% of the items in the lot. In Approach B, one critical characteristic would be verified on 80% of the items in the lot. Approach B provides a broader indication of the overall quality of the lot. Whether Approach A or Approach B should be used can vary from item to item. The types of verifications and where they will be accomplished will often dictate whether Approach A, Approach B, or a combination of both approaches is used.

#### 2.5.3 Evaluation of Results

A sampled item is considered defective if one or more critical characteristics do not meet the established acceptance criteria. The lot acceptance basis is as follows:

- The lot shall be accepted if the sample has no defectives.
- The lot shall be rejected (considered nonconforming) if the sample has one or more defectives.

The actions taken when the sample has one or more defectives are dependent on the purchaser's practices. This guideline is not intended to prescribe methods for resolving nonconforming conditions.

Possible actions when one or more defectives are found follow:

An additional sample from the remainder of the lot could be selected to determine if the nonconformance is an isolated case or a systematic problem. The additional sample size should be larger than the original sample size.

• A 100% sorting of the complete lot could be conducted. The sorting would consist of tests and inspections of each item in the lot. The sorting could be limited to the nonconforming characteristic or extend to all the critical characteristics. Items would be individually classified as conforming or nonconforming.

- An engineering evaluation can be performed to disposition the defective(s).
- The lot can be rejected and returned to the supplier in lieu of an engineering evaluation.

If an item is repaired by the supplier or the supplier provides a replacement item that is resubmitted for inspection, then special care is advised. An increased or 100% sampling of the previous nonconforming critical characteristic might be prudent.

#### 2.6 Documentation

The commercial grade item acceptance sampling process and the bases for sampling plan selection and application should be adequately documented. Documentation should address such factors as lot formation, complexity of the item, adequacy of supplier control as appropriate, safety function, test methodology, product performance, acceptance history of a supplier, item performance history, and other qualitative factors.

The following details associated with the sampling process can be documented as part of the CGI acceptance:

- Technical bases for sampling
- Lot size
- For each critical characteristic, the sample size selected or a reference to the sampling plan employed
- Sample results
- Lot disposition

#### 2.7 Trending of Sampling Results

The trending of acceptance results can be a useful tool in evaluating the effectiveness of current sampling approaches and for selecting a sampling plan approach for specific items and/or suppliers. Section 2.4 emphasizes that supplier product acceptance history is an important factor in selecting the appropriate sampling plan or approach. **Figure 2-6** illustrates in a general manner how supplier product acceptance history can have an influence on which recommended sampling plan is selected. MIL-STD-105E provides an illustration of a methodology for switching to different sampling plans based on the supplier's product acceptance history [19].
Sampling Methodology for Commercial-Grade Item Acceptance



Figure 2-6 General Relationship Between Supplier Acceptance History and the Recommended Set of Nondestructive Sampling Plans for CGI Acceptance

# 2.8 Product Overchecks

Product overchecks are random, augmented tests and inspections that can be conducted as a check to assure the item received is conforming to acceptance requirements [12]. Product overchecks are not intended to be the principal basis for acceptance. They are different from the CGI Acceptance Method 1.

Product overchecks are typically applicable to CGI procurements where acceptance is based on either a commercial-grade survey or an acceptable supplier/item performance record. In these cases, the primary bases for acceptance are:

1. <u>Commercial Grade Survey</u>: A Certificate of Conformance that the supplier has implemented the surveyed program controls.

Sampling Methodology for Commercial-Grade Item Acceptance

2. <u>Acceptable Supplier/Item Performance Record</u>: A purchaser verification that an acceptable supplier/item performance record exists.

The product overcheck is an optional verification that the supplier is continuing to provide an acceptable product. Sample sizes for product overchecks are normally small, and product overchecks are not performed on every lot received.

The test or inspection can be either nondestructive or destructive. The product overcheck can be either product- or supplier-specific. For example, periodic overchecks might be imposed on fasteners purchased irrespective of the supplier. In another case, due to recent concerns with a supplier, product overchecks might be conducted on different types of products received from that supplier.

Reasons for requiring product overchecks can include:

- The desire to verify that the supplier's controls are still effective and that the basis for acceptance is still valid.
- The previous hardware deficiencies discovered at receipt inspection, installation, or during operation.
- The issuance of United States Nuclear Regulatory Commission (USNRC) Information Bulletins and Notices related to the products being purchased or specific suppliers.
- The negative feedback on the product or the supplier provided by other utilities, industry organizations, or industry information exchanges.

The supplier-identified changes in design, materials, processes, quality commitment, manufacturing location, or organizational structure.

# **3** APPLICATION EXAMPLES ILLUSTRATING METHODOLOGY

This **Chapter** presents six application examples illustrating the methodology of selecting sampling plans to accept CGIs. The examples are structured to follow the process described in this guideline and illustrated in Figure 2-1. Each example illustrates the process of gathering data on the commercial-grade procurement, evaluating the selection factors, and making a sampling plan decision. Selection factors are addressed only if they are applicable to the example.

These examples are extensions of the six examples discussed in Exhibit 4 of EPRI NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications*. This feature allows the user to apply familiar examples to the methodology described in this guideline. The critical characteristics utilized in the examples are provided for illustration only. These critical characteristics are not intended to be all inclusive or exclusive of those that might be deemed important. The examples are provided to illustrate the methodology for selecting a sampling plan to verify the critical characteristics for acceptance of a CGI.

The examples are provided for illustrative purposes only. Another engineering evaluation of these same selection factors might result in a more stringent or less stringent sampling plan being selected.

The user is reminded that verifying the part number and performing a standard receiving inspection are integral elements of any acceptance process.

# Example Number 1: Pressure Switch, Lot Size of 20

- 1. Critical Characteristics for Acceptance and Acceptance Criteria Seven critical characteristics, including part number, are selected to be verified to accept the pressure switch for safety-related use. Verification of these critical characteristics will provide reasonable assurance that the pressure switch received is conforming. The critical characteristics and acceptance criteria for this example are as follows:
  - Pressure Range: 0 pounds per square inch (psi)-to 100 psi
  - Material, for pressure-retaining parts: commercial stainless steel
  - Enclosure, NEMA Class: NEMA 4
  - Configuration: see supplier's drawing
  - Accuracy/Deadband: ±2% of full scale
  - Electrical Ratings: 120 (VAC), 5 amperes (A)
- 2. Acceptance Method

The critical characteristics for acceptance will be verified using Acceptance Method 1 after receipt of the pressure switches.

3. Lot Formation

The pressure switches are being procured from a distributor that has maintained traceability to a single product manufacturer. The switches are being procured on one specific purchase order line item, and traceability to a single product manufacturer is a requirement. There is no assurance that the switches are from the same production lot. **Therefore, line item/single product manufacturer traceability exists.** 

- 4. Selection of Sampling Plans
  - 4.1 Consideration of Selection Factors:
  - Lot Formation

There is some confidence that the lot contains homogeneous pressure switches because (1) they are being procured on one purchase order line item and (2) the distributor maintains product manufacturer traceability. There is no assurance that the switches are from the same production lot.

# • Complexity of the Item

The pressure switches are relatively complex assemblies comprised of individual parts.

• Acceptance History

The distributor has provided several acceptable lots of other electrical items in the past. The pressure switch manufacturer has provided several acceptable lots of similar pressure switch models in the past.

Item Performance History

There is no verifiable performance history available for the pressure switch at this utility or from any other industry source. This model is a new product manufacturer design and is being procured for the first time for an upcoming design modification. The manufacturer has significant experience manufacturing pressure switches.

Cost-Effectiveness of the Tests or Inspections
 Four of the seven critical characteristics (part number, enclosure, configuration, and electrical ratings) can be readily verified using on-site special receipt tests and inspections. Two of the critical characteristics (pressure range and accuracy/deadband) must be verified through time-consuming tests using the instrumentation and control (I&C) test lab. Verification of the material for pressure retaining parts would require disassembly of the pressure switch. This disassembly would destroy the switch.

	Characteristic	Sampling Plan	Sample Size
A.	Part Number	Tightened	10
	Enclosure	Tightened	10
	Configuration	Tightened	10
	Electrical Ratings	Tightened	10
B.	Pressure Range (Full Range)	Tightened	10
	Accuracy/Deadband	Tightened	10
C.	Material	Destructive	2

## 4.2 Sampling Plan Decision

# Rationale:

- A. The Tightened Sampling Plan is selected for these characteristics for the following reasons:
  - no item performance or acceptance history exists
  - production lot traceability does not exist
  - the switch is a complex assembly
  - to readily identify gross nonconformances
  - the cost-effectiveness of the tests and inspections are high
- B. The Tightened Sampling Plan is selected for these characteristics for the following reasons:
  - no item performance or acceptance history exists
  - production lot traceability does not exist
  - the switch is a complex assembly
- C. **Using Table 2-2**, only **two pressure switches are** selected to be disassembled to verify the material of the pressure retaining parts for the following reasons:
  - line item/single product manufacturer traceability exists
  - six other critical characteristics are being verified using a Tightened Sampling Plan
  - the relatively small lot size of 20
  - the low cost-effectiveness of the test

# Example Number 2: O-Ring, Lot Size of 35

- 1. Critical Characteristics for Acceptance and Acceptance Criteria Four critical characteristics, including part number, are selected to be verified to accept the O-rings for safety-related use and environmentally qualified applications. Verification of these critical characteristics will provide reasonable assurance that the O-ring received is conforming. The critical characteristics and acceptance criteria for this example are:
  - Dimensions: ID = 5.0" (nominal) = 4.989" ±0.037, cross-section diameter = 3/8" (nominal) = 0.375" ± 0.003"
  - Material: EPDM Compound
  - Durometer Hardness: Shore A 70 ±5
- 2. Acceptance Method

The critical characteristics for acceptance will be verified using Acceptance Method 1 after receipt of the O-rings.

3. Lot Formation

The O-rings are being procured from the original host equipment manufacturer (OEM). Based on a review of an available audit report, it was determined that the OEM procures the O-rings from two different O-ring manufacturers but can furnish traceability to a product manufacturer and batch number if required. In this example, the 35 O-rings are identifiable to a specific purchase order line item. There is also traceability to a single O-ring manufacturer and batch number. The OEM can provide a sample blank of O-ring material from the original batch **which may be used for either durometer hardness verification or material verification**.

4. Selection of Sampling Plans

4.1 Consideration of Selection Factors

Lot Formation

There is high confidence that the lot contains homogeneous O-rings because of the OEM's ability to provide manufacturer and batch number traceability. The requirement to provide traceability is specified in the purchase order. **Therefore production traceability exists**.

• Complexity of the Item The O-rings are simple elastomeric seals.

Acceptance History

The OEM has provided several consecutive acceptable lots of O-rings. These lots were accepted in accordance with the utility's commercial-grade dedication procedures.

- Item Performance History Based on documented input from maintenance and other available industry information sources, this O-ring has a satisfactory and verifiable performance history.
- Cost-Effectiveness of Tests or Inspections Three critical characteristics (part number, dimensions, and durometer hardness) are readily verified on-site. Verification of material requires a destructive test performed by a third-party test facility.
- Correlation between Nondestructive and Destructive Tests For compounds used in O-ring construction, there is correlation between durometer hardness and material.

# 4.2 Sampling Plan Decision

	Characteristic	Sampling Plan	Sample Size
Δ	Part Number/Batch Number	100%	35
н. В.	Dimensions	Reduced	4
	Durometer Hardness	Reduced	4
C.	Material	Destructive	1

# Rationale:

- A. The O-rings will be shipped in a sealed plastic bag with part number and batch number identification, which can be quickly verified.
- B. The Reduced Sampling Plan is selected to verify these critical characteristics for the following reasons:
  - high confidence in lot homogeneity (batch traceability)
  - satisfactory acceptance and performance histories
  - the simplicity of the O-ring design
- C. Only one **sample** is selected to be destructively tested to verify the O-ring material for the following reasons:

- high confidence in lot homogeneity (batch traceability)
- durometer hardness, which correlates to the chemical composition of the O-ring material, is also being verified on a larger sample
- satisfactory acceptance and performance history
- the simplicity of the O-ring design
- the low cost-effectiveness of the test

# Note: In this example since a blank was furnished from the same batch, the blank could be used for the destructive test in lieu of one of the finished O-rings.

# Example Number 3: Torque Switch, Lot Size of 8

- 1. Critical Characteristics for Acceptance and Acceptance Criteria Five critical characteristics, including part number, are selected to be verified to accept the torque switch for safety-related use. Verification of these critical characteristics will provide reasonable assurance that the torque switch is conforming. The critical characteristics and acceptance criteria for this example are as follows:
  - Dimensions: 4.20" ±0.010" width, 6.50" +0.010" depth, 2.67" ±0.010" height
  - Configuration: reference is made to the product manufacturer's catalog outline drawing.
  - Material: nonmetallic parts phenolic (fibrite), dark brown color
  - Operability: transfer state at  $\pm 5\%$  of applied torque
- 2. Acceptance Methods

A source verification (Acceptance Method 3) is conducted at the product manufacturer's facility to witness activities used to control product identification (part number) and physical attributes (configuration, material, and dimensions) of the torque switches. The host equipment manufacturer is also the manufacturer of the switches. The operability of the switches will be verified using special tests and inspections (Acceptance Method 1) once the switches are received on-site.

3. Lot Formation

The torque switches are procured from the switch manufacturer, and the lot is identifiable to a specific purchase order line item. **Therefore line item/single product manufacturer traceability exists.** 

# 4. Selection of Sampling Plans

# 4.1 Consideration of Selection Factors

Lot Formation

There is confidence that the lot will contain torque switches that are homogeneous because the switches are being (1) procured from the product manufacturer and (2) examined at the same time during the source verification.

• Complexity of the Item

The torque switches are relatively complex assemblies comprised of metallic and nonmetallic parts and are used in environmentally qualified, harsh environment applications.

Acceptance History

The torque switches are infrequently procured, and little data has been maintained regarding the product manufacturer's ability to consistently provide acceptable products. No bulletins or notices have been issued addressing these items. Some indication of satisfactory acceptance history has been obtained from other industry sources.

- Item Performance History Based on documented input from maintenance and other industry information sources, this torque switch has a satisfactory and verifiable performance history.
- Cost-Effectiveness of Tests or Inspections
   Due to the complexity of the torque switch and the difficulty of verifying each
   critical characteristic using on-site special tests and inspections, as many
   characteristics as possible should be verified during the source verification.
   Many times during a source verification when an inspector is already present
   at the facility, it may be advantageous or cost-effective to verify 100% of the
   items being procured.

4.2	2	Sam	pling	Plan	Decision
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	Characteristic	Sampling Plan	Sample Size
A.	Part Number	Tightened	5
	Dimensions	Tightened	5
	Configuration	Tightened	5
	Material*	Tightened	5
B.	Operability	Verified using Post-Installation Test	8

\* Material can be verified through a review of the product manufacturer's programmatic controls rather than by witnessing a test. In this case sampling would no longer apply.

# Rationale:

- A. The Tightened Sampling Plan is selected for these characteristics for the following reasons:
  - assure homogeneity of lot
  - little acceptance history
  - complexity of assembly
  - high cost-effectiveness of the inspections during a source verification

The standard receipt inspection will verify that the torque switches received on-site are the same ones examined during the source verification.

B. Because the utility's standard post-installation test procedures require operability to be verified, this critical characteristic will be verified on all eight of the torque switches.

## Example Number 4: Valve Stem, Lot Size of 4

- Critical Characteristics for Acceptance and Acceptance Criteria
   Five critical characteristics, including part number, are selected to be verified to
   accept the valve stem for safety-related use. Verification of these critical
   characteristics will provide reasonable assurance that the valve stem is conforming.
   The critical characteristics and acceptance criteria for this example are as follows:
  - Dimensions: diameter = 1.663"  $\pm 0.001$ ", length = 6.250" +0.000 0.002"
  - Configuration: reference is made to the product manufacturer's assembly drawing.
  - Material: ASTM A276, Type 316 Stainless Steel
  - Hardness: Brinell Hardness 165 to 195 range, as specified on product manufacturer's drawing.
- 2. Acceptance Method

A commercial-grade survey (Acceptance Method 2) of the product manufacturer was conducted. The commercial-grade survey results will be utilized to verify those

critical characteristics adequately controlled by the valve stem manufacturer's commercial program. These include the dimensions and configuration of the valve stems. The critical characteristics not adequately controlled by the manufacturer will be verified using Acceptance Method 1 once the valve stems are received on-site. These include the valve stem's material and hardness.

3. Lot Formation

The valve stems are being procured from the manufacturer on a specific purchase order line item. The survey results stated that there is no assurance that the valve stems supplied will be from the same production lot. **Therefore line item/single product manufacturer traceability exists.** 

4. Selection of Sampling Plans

4.1 Consideration of Selection Factors

Lot Formation

There is little confidence that the lot contains homogeneous valve stems because there is no assurance that the stems are from the same production lot and the commercial-grade survey identified concerns over the manufacturer's material controls.

- Complexity of Item The valve stems are relatively simple, metallic replacement parts.
- Acceptance History The manufacturer has provided several acceptable lots of valve stems in the past.
- Item Performance History Based on documented input from maintenance and other industry information sources, this valve stem has a satisfactory and verifiable performance history.
- Cost-Effectiveness of Tests or Inspections The critical characteristics can be readily verified based on the commercial-grade survey results or by on-site nondestructive special tests and inspections.

	Characteristic	Sampling Plan	Sample Size
A.	Part Number Material Hardness	Tightened Tightened Tightened	3 3 3
B.	Dimensions Configuration	N/A N/A	

#### 4.2 Sampling Plan Decision

#### Rationale:

- A. The Tightened Sampling Plan is selected to verify these critical characteristics for the following reasons:
  - the commercial-grade survey results identified that these characteristics were not being adequately controlled
  - to **increase confidence in** the homogeneity of the lot
  - the high cost effectiveness of the tests and inspections
- B. Because these characteristics are being verified using the results of a commercial survey, a sampling plan does not apply.

## Example Number 5: Resistor, Lot Size of 150

- 1. Critical Characteristics for Acceptance and Acceptance Criteria Five critical characteristics, including part number, are selected to be verified to accept the resistor for safety-related use. Verification of these critical characteristics will provide reasonable assurance that the resistor is conforming. The critical characteristics and acceptance criteria for this example are as follows:
  - Resistance:  $\pm 10\%$  of 10,000 ohms ( $\Omega$ ) rated resistor
  - Power Rating: 10 watts (W)
  - Markings: brown, black, orange, double space, silver, and JAN markings
  - Configuration: reference is made to the product manufacturer's catalog outline drawing

2. Acceptance Method

The critical characteristics for acceptance will be verified using Acceptance Method 1 once the resistors are received on-site.

3. Lot Formation

The resistors are procured from a distributor. The purchase order specifies a reliability-based military specification and requires the manufacturers to be on the qualified products list (QPL). The lot is identifiable to a specific purchase order line item. The QPL-listed distributor supplies resistors from several QPL manufacturers. **Therefore line item/multiple manufacturers traceability exists.** 

4. Selection of Sampling Plans

4.1 Consideration of Selection Factors

Lot Formation

There is some confidence that the lot could be considered homogeneous because the resistors are manufactured to a military specification by QPL product manufacturers. The QPL program requires the product manufacturer to qualify the product and freeze the design, materials, and processes. The required military specification requires ongoing reliability testing. Some variation might exist because the resistors can be supplied by different QPL product manufacturers.

- Complexity of Item The resistors are simple electronic devices with no moving parts.
- Acceptance History

The distributor has provided many consecutive acceptable lots of resistors in the past. These resistors were accepted in accordance with the utility's commercial-grade dedication program.

- Item Performance History Based on documented input from maintenance and other industry information sources, this resistor has a satisfactory and verifiable performance history.
- Cost-Effectiveness of the Tests or Inspections The tests required to verify the marking, configuration, and resistance are readily performed on-site and are nondestructive. The test required to verify power rating is considered a destructive test by this utility.
- Applicability of Industry Standards The resistors are manufactured to a reliability-based military specification by

QPL product manufacturers, which provides some assurance that the resistors will be uniform.

4.2 Sampling Plan Decision

	Characteristic	Sampling Plan	Sample Size	
A.	Part Number* Markings Configuration Resistance	Normal Normal Normal	26 26 26	
B.	Power Rating	Destructive	4	

\* Part number will be verified on shipping container.

# Rationale:

- A. The Normal Sampling Plan is selected to verify these critical characteristics for the following reasons:
  - the high cost effectiveness of the tests and inspections
  - satisfactory performance history
  - satisfactory acceptance history
  - to identify gross nonconformances
  - to reasonably assure the homogeneity of the lot
  - the resistors are manufactured to a military specification by QPL product manufacturers
- B. Referring to sampling option 1 described in Section 2.4.4 of this guideline, a maximum of thirteen (13) resistors would have to be destroyed to achieve reasonable assurance that the power rating characteristic was conforming. However, other positive factors were considered and further reduction of the sample size was deemed appropriate. In particular, the manufacturing per national standards and the use of QPL product manufacturers provided higher confidence in the homogeneity of the lot than what might be expected from a distributor providing line item/multiple product manufacturers traceability. Therefore, considering these and the other positive factors noted below, use of

**Table 2-2 was justified. Thus only four** resistors are selected to be destructively tested to verify the power rating:

- the satisfactory acceptance history
- the possibility the resistors might come from different product manufacturer
- the satisfactory and verifiable performance history
- the item was manufactured to a military specification by QPL product manufacturers
- four other characteristics are being verified using the normal plan
- **after verification of the other characteristics with larger samples**, there is now **higher confidence in the** homogeneity of the lot.

# Example Number 6: Pressure Transmitter, Lot Size of 18

- 1. Critical Characteristics for Acceptance and Acceptance Criteria Six critical characteristics, including part number, are selected to be verified to accept the pressure transmitter for safety-related use. Verification of these critical characteristics will provide reasonable assurance that the pressure transmitter is conforming. The critical characteristics and acceptance criteria for this example are:
  - Pressure Rating: 150 psi
  - Pressure Range: 50 psi-150 psi
  - **Pressure Boundary** Materials: commercial stainless steel, Buna-N seals
  - Accuracy: ±2.5% of full scale
  - Electrical Ratings: 120 VAC, 5 A contact rating, 4 milliamperes (mA)–20 mA output
  - Configuration/**Dimensions**: reference is made to the product manufacturer's catalog outline drawing

## 2. Acceptance Method

The critical characteristics for acceptance will be verified using Method 1 after receipt of the pressure transmitters.

3. Lot Formation

The pressure transmitters are being procured from a manufacturer that can provide

traceability to a specific transmitter production lot by means of serial number identification. The lot is also identifiable to a specific purchase order line item. **Therefore production traceability exists**.

4. Selection of Sampling Plans

4.1 Consideration of Selection Factors

Lot Formation

There is high confidence that the lot contains pressure transmitters that are considered homogeneous because of the traceability to a specific product manufacturer and product manufacturer production lot.

- Complexity of Item The pressure transmitters are relatively complex assemblies comprised of many parts.
- Acceptance History

The acceptance history of the pressure transmitters has been satisfactory, but there have not been any procurements of the transmitters in the past three years. During that time, the product manufacturer was purchased and underwent extensive organizational and operational changes.

• Performance History

Based on documented input from maintenance and other industry information sources, this pressure transmitter has a satisfactory and verifiable performance history.

- Cost-Effectiveness of the Tests or Inspections The critical characteristics, with the exception of the material, are readily verified through special receipt tests and inspections. Verification of the material requires disassembly of the pressure transmitter. This disassembly would render the transmitter unusable.
- Correlation Between Critical Characteristics A test to verify the pressure integrity of the pressure transmitter has been added to reduce the number of transmitters disassembled to verify the material of pressure retaining and seal parts.

# 4.2 Sampling Plan Decision

	Characteristic	Sampling Plan	Sample Size
A.	Pressure Range	Normal	5
	Accuracy	Normal	5
	Electrical Rating	Normal	5
	Configuration/Dimensions	Normal	5
	Pressure Rating	Normal	5
B.	Pressure Retaining/ Seal Material	Destructive	1

#### Rationale:

- A. The Normal Sampling Plan is selected to verify these characteristics for the following reasons:
  - the high confidence in the device lot homogeneity
  - the relative complexity of the transmitters
  - the lack of recent acceptance history
  - the satisfactory and verifiable performance history
  - the relatively high cost effectiveness of these nondestructive tests
- B. One pressure transmitter is selected to be destructively tested to verify the material of the pressure retaining pieces and the Buna-N Seal for the following reasons:
  - the low cost effectiveness of the destructive test
  - the high confidence in the device lot homogeneity
  - the correlation between the device's pressure integrity and the material of those parts
  - the satisfactory and verifiable performance history
  - the verification of four other critical characteristics

# **4** GLOSSARY OF TERMS AND DEFINITIONS

The terms presented below are referenced in various sections of this guideline and are used within the context of these definitions.

Acceptable Quality Level - The quality level that, for purpose of sampling inspection, is the limit of a satisfactory process average - (Paraphrased from ANSI/ASQC Standard Q3-1988)

Acceptable Supplier/Item Performance Record - A record of acceptable performance of a supplier's CGI that provides justification for a purchaser to accept the item for safetyrelated use. (From EPRI NP-5652, subject to the conditions of Nuclear Regulatory Commission (NRC) Generic Letter (GL) 89-02)

Acceptance - The employment of methods to produce objective evidence which provides reasonable assurance that a commercial grade item received is the item specified. (From EPRI NP-5652)

Basic Component - An item procured either as a safety-related item or as a commercial grade item which has been accepted and dedicated for safety-related application. This term is synonymous with "safety-related component" (From EPRI NP-5652)

Commercial Grade Item - A structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component - CGI's do not include items where the design and manufacturing process require many in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e - one or more critical characteristics of the item cannot be verified. (Ref - 10CFR21, Rev - 2)

Commercial Grade Survey - Activities conducted by the purchaser or its agent to verify that a supplier of commercial grade items controls, through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept those items for safety-related use. (From EPRI NP-5652 subject to the conditions of Nuclear Regulatory Commission Generic Letter 89-02)

Cost-Effectiveness - The value of information provided by a specific sampling plan compared to the sum of the (1) sample costs and (2) test or inspection costs.

#### Glossary of Terms and Definitions

Critical Characteristics - Identifiable and measurable attributes/variables of a commercial-grade item, which once selected to be verified, provide reasonable assurance that the item received is the item specified. (From EPRI NP-5652)

Defect - Any nonconformance of the unit of product with specified requirements - (From MIL-STD-105E)

Defective - A defective is a unit of product that contains one or more defects - (From MIL-STD-105E)

Distributor - An intermediate supplier between the product manufacturer and the purchaser. The distributor normally only performs a warehousing and distribution function.

Engineering - Individuals with the appropriate capabilities and responsibilities to make technical decisions. This is not meant to prescribe that only individuals who are part of a formal engineering organization should perform "engineering" activities. (See EPRI NP-6629)

Item - Any level of unit assembly, including structures, systems subsystems, subassembly, component, part, or material. (From ANSI N45.2.10-1973)

Limiting Quality - When a lot is considered in isolation, a 0 quality level that, for the purpose of sampling inspection, has a low probability of acceptance. (From ANSI/ASQC Standard Q3-1988)

Lot - The term lot shall mean "inspection lot," that is, a collection of units of product from which a sample is to be drawn and inspected and can differ from a collection of units designated as a lot for other purposes (for example, production, shipment, etc.). (Paraphrased from MIL-STD-105E)

Process Average - The average percent defective of product submitted by the supplier for original inspection. (Paraphrased from MIL-STD-105E)

Production Lot - That part of one manufacturer's production made from the same nominal raw material under essentially the same conditions and designed to meet the same specifications. (From ASTM D4392-84)

Product Manufacturer - The organization that manufactures the item to be accepted and has primary responsibility for product performance.

Sample - A sample consists of one or more units of product drawn from a lot with the units of the sample being selected at random without regard to their quality. The

number of units of product in the sample is the sample size. (Paraphrased from MIL-STD-105E)

Source Verification - Activities witnessed at the supplier's facilities by the purchaser or its agent for specific items to verify that a supplier of a CGI controls the critical characteristics of that item, as a method to accept the item. (From NP-5652)

Special Tests and Inspections - Activities conducted after receipt of a CGI to verify one or more critical characteristics as a method to accept the item for safety-related use. (From NP-5652)

Standard Receipt Inspection - Activities conducted upon receipt of items, including CGIs, in accordance with ANSI N45.2.2-1978 or ANSI/ASME NQA-1-1986 and NQA-2-1986 to check such elements as the quantity received, part number, general condition of items, and damage. (From NP-5652)

Supplier - The organization furnishing an item to be accepted. This could include an original equipment manufacturer, product manufacturer, or distributor. (From NP-5652)

Technical Evaluation - An evaluation performed to assure that the correct requirements for an item are specified in a procurement document. (From NP-5652)

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# **A** ALTERNATIVE TYPES OF SAMPLING METHODOLOGIES

This appendix briefly discusses a number of alternate sampling methodologies that can be considered in addition to the sampling approaches discussed in this guideline. Appendix Section A.1 discusses four subjective or empirically based sampling approaches that have been utilized for acceptance sampling. These plans are called Rule-of-Thumb sampling plans. Some of the more popular published sampling documents are briefly reviewed in Appendix Section A.2. A more detailed discussion of the use of EPRI Report NP-6200 is included to illustrate how this document could be employed for commercial-grade item (CGI) acceptance sampling.

# A.1 Rule-of-Thumb Sampling Plans [15]

Sampling plans which that are empirically or subjectively derived are commonly called Rule-of-Thumb sampling plans. Although they can appear to be logical, especially if previous history is included in their development, they might not be statistically sound.

A typical example of a Rule-of-Thumb plan would be to require a 10 percent (%) sample of each incoming lot regardless of lot size. Statistically, the sampling risks will not be constant as because lot size varies. Such a sampling plan might give an inadequate level of assurance at small lot sizes and an unnecessarily high level of assurance at large lot sizes.

Despite the plans being empirically or subjectively derived, they are often satisfactory for the small lot sizes that are infrequently received. Rule-of-Thumb plans also are useful for establishing sample sizes when a source verification is required.

The simplicity of Rule-of-Thumb plans often compensates for the variability in risk of making a proper acceptance decision. For CGI acceptance, the use of sound technical judgment and consideration of the selection factors discussed in Section 2.4.2 can assure that the sample sizes selected are reasonable.

Examples of Rule-of-Thumb-type sampling plans follow:

#### Alternative Types of Sampling Methodologies

## • Percentage Plans

A certain percentage of items submitted are sampled regardless of lot size. The percentage can vary with the type of critical characteristic or previous acceptance results. For example, during source inspection's, an organization' policy is to verify dimensions on 10% of the lot presented. Because items on the previous visit had unacceptable dimensions, the sample size is increased to 25% on this visit.

# • Periodicity Plans

These plans are based on periodic verification testing or inspection of received lots. For example, a sampling plan might require one barrel of oil supplied by Company X to be tested each calendar quarter. There is no statistical justification for such a plan since because the barrels received during the quarter could range from 1 to perhaps 100 barrels. Nevertheless, such plans might be adequate if the following conditions are met:

- 1. The quality history record of the product has been satisfactory.
- 2. The product is standardized.
- 3. Testing is difficult or the cost/benefit does not warrant increased testing.
- 4. Shipments of the product are typically received during the sampling period.

## Frequency Plans

These plans require the testing or inspection of a product on a certain frequency. For example, every one hundredth fuse received is sent out for destructive testing. If small lot sizes are being purchased, there might be several shipments where the fuse testing will not be required. If the purchased lot sizes are large, then several samples might be tested on one shipment (that is, a shipment of 300 fuses would require three tests).

## Case-by-Case Plans

Often, the sample size is determined using technical judgment at the time the acceptance plan is developed. For example, 10 pump impellers are being ordered. The sample size specified for each pump impeller critical characteristic to be verified is established without any reference to a sampling plan. Engineering judgment is used to decide on a sample size for each selected critical characteristics. The selection factors in Section 2.4.2 should be considered to assure that the sample size selected are reasonable.

# A.2 Overview of Certain Published Acceptance Sampling Plans

# A.2.1 MIL-STD-105E, "Sampling Procedures and Tables for Inspection by Attributes"

MIL-STD-105E is the most frequently used and well-known attributes sampling document. The sampling plans contained in MIL-STD-105E are used extensively for accepting both military and commercial products. Despite its widespread use, the document is often misinterpreted. Special care must be exercised when reading the sampling plan tables to determine the correct sample size.

MIL-STD-105E also requires that several subjective assumptions and decisions be made. They include:

# 1. Choosing the Appropriate Sampling Level

Three general inspection levels and four special inspection levels are provided. General inspection Level II is considered the normal inspection level. Single, double, and multiple sampling plans are provided. Single sampling plans are most frequently used.

# 2. Choosing the Acceptable Quality Level

The Acceptable Quality Level (AQL) is the maximum process average (average percent defective) considered acceptable. AQLs based on process averages from 0.010 to 10 can be selected. The appropriate AQL must be designated before a plan can be used. An AQL expressed in a form of defects per hundred units can also be designated. The AQL concept included in MIL-STD-105E was developed considering sampling of a continuous series of lots. Nuclear procurement normally involves infrequent, isolated lots.

## 3. Switching Procedures

For a given sampling level, MIL-STD-105E allows the switching from Normal to Tightened or Reduced Sampling Plans based on the results of previous inspections. For example, when normal inspection has been in effect, tightened inspection is required when 2 out of 2, 3, 4, or 5 consecutively submitted lots have been rejected.

An example of how a MIL-STD-105E sampling plan would be designated follows:

AQL = 4.0, Single Sampling, Normal Inspection Level II

# A.2.2 Dodge-Romig Sampling Tables

Dodge and Romig describe in the subject document four sets of attribute sampling plans. The Lot Tolerance Percent Defective (LTPD) single sampling plan is probably the

Alternative Types of Sampling Methodologies

most useful one. Each plan was devised to require the minimum total inspection for S a product of a given process average. The LTPD plans are designed to provide considerable assurance that individual lots of poor quality will not be accepted.

Some limitations of these tables follow:

- An estimated process average must be determined. The estimated process average is intended to be established based on a review of past performance. Reliable information to develop an estimated process average is normally not available for nuclear procurement because of the infrequency of purchases.
- The plans require the sorting of the remainder of the items in the lot if the sample is rejected.
- The sample sizes for small lot sizes are normally 100%. For example, the single sampling table for a lot tolerance percent defective of 5.0% and an estimated process average of 2.5% requires lot sizes from 1–30 to be 100% verified.

# A.2.3 MIL-STD-414, "Sampling Procedures and Tables for Inspection by Variables for Percent Defective"

MIL-STD-414 is a variables sampling plan. A specified characteristic is evaluated using the plans. The characteristic must be capable of being measured on a continuous scale. A recording of the specific measurement is mandatory in order to use the tables. An index number is calculated using the recorded measurements. The index number is then compared against an acceptance value to determine if the lot should be accepted based on the characteristic measured.

Like MIL-STD-105E, an inspection level must be selected. The document lists five different levels. Level IV is the normal inspection level. An AQL must also be designated. The appropriate plan to be used also depends on whether or not the variability of the product being received is known or not. A known variability would require records of past measurements and the calculation of the historical variation.

Useful examples are provided in the standard. The standard explains the necessary steps and calculations. Variables sampling plans require smaller sample sizes than comparable attribute sampling plans.

Limitations of MIL-STD-414 for nuclear procurement applications are:

• The standard is not user-friendly. A sound understanding of statistics is needed to properly utilize the document.

- The calculations involved are time-consuming. Programmable calculators would be needed to minimize calculation time and errors.
- Since MIL-STD-414 only applies to variables, other sampling plans would be needed for attributes.
- The actual recording of each measurement is required to use MIL-STD-414. The recording of actual measurements is not mandatory for attribute sampling plans.

MIL-STD-414 has advantages when purchasing frequent shipments of the same product from a supplier. For the small, infrequent shipments involved in nuclear procurement, incorporating variables sampling plans is not normally cost cost-effective.

# A.2.4 EPRI NP-6200, "A Performance-Based Selective Inspection Process"

NP-6200 was developed for the nuclear industry to provide a selective inspection process to assess the quality of nuclear power plant items. The primary purpose of the document was to provide a reasonable sampling process for verifying plant installations.

The selective inspection plan in NP-6200 is based on one of five continuous sampling plans continued in MIL-STD-1235B, "Single and Multi-level Continuous Sampling Plans." Plan CSP-V in MIL-STD-1235B was used as the basis.

Although the plan was developed to inspect completed plant installations, the plan could have applicability to acceptance sampling.

The primary advantage of the selective inspection process is that the number of items sampled over time could be significantly reduced if no discrepancies were found in the samples. The drawback of the selective inspection process when applied to acceptance sampling is that the sampling process is better suited for large quantities of items frequently purchased.

A brief discussion of how EPRI Report NP-6200 could be applied to acceptance sampling follows. NP-6200 should be consulted for more specific guidance.

The following key definitions from NP-6200 are important when using the referenced selective inspection process:

# • Percent Acceptable

The lowest value for the proportion of non-discrepant items in the population, expressed in percent, that is considered acceptable.

#### Alternative Types of Sampling Methodologies

# • Screening Inspection

During screening inspection, every consecutively released item for inspection must be inspected.

# • Selective Inspection

During selective inspection, only one of several items released for inspection, based on a selection frequency (f), is inspected.

# • Selective Frequency (f)

Selection frequency is stated in the form (f) = 1/K. It means from every K units of lot released for inspection, one randomly chosen work item will be inspected. Example: (f) = 1/3 means for every three work items, one randomly chosen item will be inspected.

# • Clearance Number (i)

When screening inspection is in effect in the initial phase, the number of consecutively released items for inspection that must be found to be free from discrepancies before selective inspection is instituted. This number is also used during selective inspection in the initial phase to change to the continuing phase of the process, when the number of consecutively inspected items without discrepancies equals this number.

# • Reduced Clearance Number (x)

When the selective inspection process is in the continuing phase and a selected item is j discrepant, the reduced clearance number (x) identifies the j number of consecutive non-discrepant items that must be found in the screening inspection in order to remain in the continuing phase.

Figure A-1 contains a detailed flowchart of the process. (The flowchart is Figure 3-3 in NP-6200.) The selective inspection process has an initial phase and a continuing phase. Satisfactory sample results must be obtained before moving into the continuing phase.

Before beginning the process, the following subjective variables have to be specified.

- **Percent Acceptable:** Table 3-1 in NP-6200 provides six possible levels from 99% to 90%.
- **Population:** Population ranges are listed in NP-6200, Table 3-1. For acceptance sampling, the number of like items to be purchased from a supplier over a designated period of time (for example, one year) would have to be estimated.
- **Time Period:** The selective inspection process is a continuous sampling plan. This plan should probably not be utilized unless shipments of the product are being received at least quarterly.

#### Alternative Types of Sampling Methodologies







**Continuing Phase** 



Figure A-2 Detailed Flowchart of Selective Inspection Procedure

An example will be used to illustrate the process. The selected variables are:

Percent Acceptable	90
Population Interval	91-500
Time Period	An average of three shipments are received a
	quarter.

From Table 3-1 of NP-6200, the following values are obtained:

Clearance Number	$\mathbf{i} = 9$
Reduced Clearance Number	<b>x</b> = 3
Selection Frequency	f = 1/7

For the purpose of this example, a lot of 25 items is received. The process will be illustrated for one shipment, but although it would be continued over consecutive shipments. A discrepant item would be an item with one or more nonconforming critical characteristics.

The initial phase would start with a screening inspection. During the screening inspection, each item randomly selected from the lot would be subject to the special tests and inspections. Once a consecutive number of acceptable items equal to the clearance number of i = 9 is reached, the selective inspection phase would begin. If there were any discrepant items during the screening inspection, 100% inspection would continue.

During the selective inspection step, the selective frequency f = 1/7 would govern the sample selection. One of the next seven items in the lot would be sampled. If a defective were found, the sampling process would return to the 100% screening inspection step.

If during the selective inspection steps the number of selectively and consecutively inspected items equals the clearance number of i = 9, then the process would go to the continuing phase.

The continuing phase would start with a selective inspection at the frequency f = 1/7. If none of the selectively inspected items were discrepant, the process would continue. If a discrepant item were found during the selective inspection step of the continuing phase, then a screening inspection would be instituted. The screening inspection would start with the next item and continue until the number of non-discrepant items equaled the reduced clearance number x = 3. At this point, the selective inspection at a frequency of f = 1/7 would recommence. If a discrepant item were found during the screening inspection before the reduced clearance number were reached, then the sampling process spacing would return to the beginning of the initial phase.

#### Alternative Types of Sampling Methodologies

For the lot of 25, the sampling pattern would be similar to the following—assuming no discrepant items were found:

1. P	10	19
2. P	11	20
3. P	12	21
4. P	(f=1/7)13	22
5. P	14	23 P
6. P	15	24
7. P	16 P	25
8. P	17	
(i=9) 9. P	18	

The first nine items would be sampled 100% as part of the screening inspection. After nine consecutive items were found free of discrepancies as designated by the Ps, the selective inspection step would begin. Items would be sampled on a frequency of every seventh item. If a discrepant item were found, then the sampling process would return to the screening inspection step. If no discrepancies were found in the next nine selectively inspected items, then the continuing phase could commence. This process would continue when future shipments of the same items were received.

# **B** LOT FORMATION

Lot formation can be important in providing justification for using a specific sampling plan. The degree of lot homogeneity influences the extent of sampling required [11, 16]. By up-front communication with the supplier and proper specification of lot formation requirements in the purchase order, assurance of homogeneity of the received lot can be maximized and acceptance costs minimized.

General guidance on the relationship between the **three** types of lot formations (see Section 2.3) and sampling approaches follows. As illustrated in **Chapter** 3, consideration of the additional selection factors discussed in Section 2.4.2 might result in a different sampling approach than suggested below.

Examples are provided for each type of lot formation. Information on how a product manufacturer produces, controls, and identifies its products are important in justifying a lot formation decision. The examples describe certain sources that can be used to **support** lot formation. These sources can include **the following**:

- commercial grade survey reports
- audit reports
- product manufacturer catalogs
- product manufacturer procedures
- national standard requirements
- physical markings
- certified material test reports
- written communications

When distributors are involved, information on distributor stocking controls and supply practices might also be necessary. This document is not meant to imply any specific practice is preferred, but it is suggested that some verification of the information used as the basis of lot formation be performed.

# **B.1 Production Traceability**

This type of lot formation provides the highest confidence that items in a lot are homogeneous. Items assigned a heat number, production lot number, or batch number are typically manufactured to the same requirements, using the same product manufacturer controls, and at essentially the same time. When production traceability exists, a small representative sample is normally sufficient to assure that a critical characteristic is conforming. For nondestructive tests and inspections, the Reduced Sampling Plan should be considered unless there are overriding selection factors. For destructive tests and inspections, a sample size of one is normally sufficient.

Examples of lot formation based on production traceability follow:

- 1. A purchase order line of 20 fasteners was found to be traceable to a single product manufacturer by head markings and a single production lot by head markings to Heat Code NX-1. NX-1 was traceable by the product manufacturer's certification to the original raw material and all heat treatment records. Additional fasteners on a later purchase order of the same diameter, but a different length, were also identified as having the same heat code. The utility could choose to treat both line item orders as a single lot for sampling purposes.
- Two boxes, containing 16 tubes per box, of RTV 108 were identified by the same batch number. The product manufacturer maintained excellent control of material batches and that the unique identification was representative of a production lot. All 32 tubes of the RTV 108 would be considered as a single production lot for sampling purposes.
- 3. Five pieces of 1/2" low strength carbon steel plate were procured on a single purchase order line item from an authorized distributor. Two plates were stamped with E120034-2, and three plates were stamped with #120034-4. Although the steel mill maintained an excellent transfer program of heat numbers, but no mention of the suffix numbers after the dash was found. The product manufacturer's quality assurance manager stated in a Telecon that the suffix number is indicative of the slab number poured from the heat in the ingot pour process. It was also determined that the particular grade of steel required no additional heat treatment after rolling. The utility could treat all five plates as a single production lot for sampling purposes.
- 4. A pressure switch manufacturer supplied 10 switches on a single purchase order line item to the same specifications. All 10 switches were serialized, but five switches were identified to one production lot number while the other five switches were identified to another production lot number. A conversation with a product engineer at the factory established that the product manufacturer had a program for maintaining batch control of parts for the manufacture of whole components. The
production lot number was traceable to the specific parts used in the manufacture of the switch production lot. The utility could treat each set of five switches as a single production lot for sampling purposes.

Heat number, production lot number, or batch number traceability can be obtained for many commercial-grade products; however, up-front planning and research need to be performed during the purchase requisition stage. The type of traceability required should be specifically stated in the purchase order.

## B.2 Line Item/Single Product Manufacturer

This type of lot formation provides some evidence of homogeneity because the same product manufacturer has produced the item. For product manufacturers with formalized controls (for example, quality control programs and statistical process control programs) similar product controls should be exercised on all production runs. For nondestructive tests and inspections, the Normal Sampling Plan should be considered based on this type of lot formation. For destructive tests and inspections, refer to Section 2.4.4.

Examples of line item/single product manufacturer lot formations follow:

- 1. A purchase order line item quantity of 250 fuses of the same type and rating, among other things, were identified by the same date code. A review of the commercial-grade survey report revealed that the manufacturer coded each day's production run but performed the in-house quality control inspections on a random basis without regard to date codes. The utility could treat the 250 fuses as a line item from a single product manufacturer.
- 2. A quantity of 5,000 self-drilling anchors was purchased as a single line item from a distributor. The anchors were drop-shipped from the product manufacturer's facility. The anchors were boxed in groups of 50 each, and the boxes included a date stamp and the product manufacturer's name. In Telecons, it was determined that the product manufacturer performed in-house quality control inspections per date code but that multiple heats of material or different heat treat lots could be mixed within a date coded lot. The utility could treat the 5,000 anchors as a line item from a single manufacturer.
- 3. Four pressure transmitters were procured from an authorized distributor as a single line item to an identical specification. Nameplate data included ratings and a serial number. Attempts at information retrieval via Telecon were unsuccessful, and the survey report obtained from another utility mentioned that the serialization was performed by quality control after unit testing. No other details were available; therefore, the assumption was made that each transmitter could be manufactured

#### Lot Formation

from different production lots of parts. Because of the relationship of serialization to tested performance, the utility could treat the four transmitters as a line item from a single manufacturer.

4. Terminal lugs were ordered in various quantities on a contract with a local distributor. Some item quantities were changed to match the number contained in boxes (100 each). Those line items specifying at least 500 terminal lugs and whole box quantities were direct-shipped from the product manufacturer. The several line items specifying quantities under 500 or with odd numbers came from the distributor stock. Terminal lugs from the product manufacturer came in clearly identified and unopened boxes. Those supplied by the distributor came in plain Ziploc<sup>®1</sup> bags or in boxes that had been opened. Although no survey of the product manufacturer was available, the utility had been using that brand of terminal lug since construction days at all three sites and went so far as to specify the brand name in engineering procedures for installation. Therefore, based on the successful product history and the acceptable supply and packaging of the product manufacturer, the utility could treat the terminal lugs from the product manufacturer as a line item from a single product manufacturer. The terminal lugs from the distributor would be treated as a line item from multiple product manufacturers due to the supply by a distributor and the packaging.

When items are ordered from a distributor, it is recommended that the purchase order specify a specific product manufacturer or require the items to be from only one product manufacturer.

# B.3 Line Item/Multiple Product Manufacturers

These lots are typically provided by a distributor. Greater risks exist in assuming homogeneity because variations in product conformance can exist between different product manufacturers even though they are providing like-items [16]. For these lots, the Tightened Sampling Plan should be considered for nondestructive tests and inspections. Satisfactory distributor product acceptance history or common production to a national standard, however, can justify the use of the Normal Sampling Plan. For destructive tests and inspections, refer to Section 2.4.4.

Examples of line item/multiple product manufacturer lot formations follow:

1. Capacitors were supplied on a single purchase order line item from a local distributor. Receipt inspection found several manufacturers' identification markings on the ordered capacitors. The capacitors could be treated as a line item from

<sup>&</sup>lt;sup>1</sup> Ziploc is a brand name of DowBrand, a subsidiary of the Dow Chemical Company.

multiple product manufacturers due to the various manufacturers' identification markings.

- 2. Military reliability standard resistors were ordered as a single line item from a qualified products list (QPL) distributor. The quantity required exceeded the distributor stock from a single product manufacturer, and the need date prohibited waiting for further stock. The distributor was unaware of the utility's desire to maintain separate demarcation by product manufacturer until it was too late. The distributor had bagged all the resistors from two QPL product manufacturers for shipment. Visual examination determined that reliable separation by product manufacturer was not possible. The utility could, therefore, treat the resistors as a line item from multiple manufacturers for sampling purposes.
- 3. Several thousand structural fasteners were ordered to an ASTM standard on a line item from a local supplier. The fasteners were received in boxes that showed obvious signs of having been opened. Inspection revealed that the color differences of the bolts was fairly obvious and further comparisons identified several manufacturer's head markings. In this case, the utility could chose to treat the fasteners as a line item from multiple manufacturers for sampling purposes.
- 4. A fairly large order of stainless steel spiral-wound gaskets with centering rings were ordered from the valve OEM by reference to such things as the applicable valve drawings, serial numbers, code of record and OEM part number. The commercial-grade survey report indicated that the valve manufacturer maintained poor control over commercial-grade, non-ASME Code items. For a previous order of gaskets (of a different size) from the OEM, the utility had found that various spiral-wound gaskets from two product manufacturers had been supplied. This utility discovery was made by the quality control inspector due to apparent differences in the weld quality and metal color. Due to the previous history and survey knowledge, the utility could treat the gaskets as a line item from multiple manufacturers for sampling purposes.

Whenever possible, this type of lot formation should be avoided by requesting in the purchase order that the line item be from one product manufacturer. This procurement practice can justify the use of smaller sample sizes with resultant inspection cost savings.

# **C** BASIS FOR SAMPLING PLANS

### C.1 General

The risks associated with any sampling plan are determined by the following three factors:

- Sample Size
- Accept/Reject Numbers
- Lot Size

Sample size has the greatest impact on the ability of a sampling plan to assess the acceptability of a lot. In general, the greater the sample size, the lower the consumer's risk, which is the probability that a bad lot will be accepted [16].

The second factor is the designated accept/reject numbers [19]. A plan can be designed to allow the acceptance of a lot if the number of defectives are less than or equal to a specific number. For example, a plan might specify an acceptance number of three and a rejection number of four. This means that if the sample has three or less defectives, then the lot will be accepted. If the sample has four or more defectives, the lot will be rejected.

The final factor, lot size, has a negligible effect on the sampling plan as long as the sample size is a small percentage of the lot size.

The risks associated with a given sampling plan can be shown on an operating characteristic (OC) curve. The curve is a plot of the probability of acceptance ( $P_a$ ) versus the percent defective in submitted lots. The curve is prepared for a specific sample size and accept/reject numbers. Figure C-1 provides an illustration of a hypothetical operating characteristic curve.





Quality indices have been developed as an aid in evaluating and specifying acceptance sampling plans [16]. The Acceptable Quality Level (AQL) and Limiting Quality (LQ) levels are two important indices.

An AQL is the quality level that, for the purpose of sample inspection, is the limit of a satisfactory process average [1]. For example, if 4% is the maximum process average of defectives considered acceptable, this would be defined as an AQL 4.0. The probability of accepting a lot at the designated AQL value is high. In most plans, there is a 95% probability of accepting a lot at the designated AQL. At a 95% AQL, there is a 5% risk that a good lot will be rejected. This is called the producer's risk. For a given AQL,

different combinations of sample sizes and corresponding accept/reject numbers are possible.

An LQ is a quality level that, for purposes of sampling, has a low probability of acceptance [1]. An LQ level has different titles in other references, such as Lot Tolerance Percent Defective or Rejectable Quality Level [8,15]. If the supplied lot has a percent nonconforming equal to or worse than the LQ, then there is a low probability of accepting the lot. This probability is called the consumer's risk. Typically consumer's risks of 10% or 5% are used. It is extremely important to recognize that the consumer's risk is <u>not</u> the probability the purchaser will actually receive items at the LQ level [15]. The consumer's risk only means that if a lot with LQ percent defectives is received, then the lot will be rejected 90% of the time. Lots with no defectives or well below a sampling plan's LQ level are expected from reputable suppliers.

The hypothetical OC curve provided in Figure C-1 illustrates how the AQL and LQ level can be determined from the OC curve. The AQL has a 95%  $P_a$ . The LQ level has a 10%  $P_a$ . For a fixed accept/reject number, the AQL and LQ will improve (decrease in value) with an increase in sample size. The LQ improves more significantly than the AQL with a sample size increase.

An excerpt from Nakano and Marshall illustrates these changes for a single sampling plan with an acceptance number of zero [21]. (The table is based on an AQL with a 95%  $P_a$  and a consumer's risk of 10%.)

AQL	LQ
5.00	90.01
2.53	68.38
1.70	53.59
1.27	43.77
1.02	36.91
0.85	31.88
0.73	28.04
0.64	25.02
0.57	22.08
0.51	20.57
	AQL 5.00 2.53 1.70 1.27 1.02 0.85 0.73 0.64 0.57 0.51

As can be seen from the table, the AQLs can be quite good even at small sample sizes. The LQ levels, however, can be high. This is a risk that must be tolerated unless 100% inspection is specified.

The above factors affecting sampling plan discrimination were considered when developing the three recommended sets of nondestructive sampling plans provided in Section 2.4.3.

The plans incorporate a progressive (that is, 1, 2, 3) sample size increase. Most published sampling plans have quantum jumps in sample sizes as the lot range changes. For example, in MIL-STD-105E, Table II-A, the first five sample sizes jump 2, 3, 5, 8, and 13 with each increase in lot size. Such quantum jumps result in wide variations in the percentage of samples taken as lot size changes.

Selective OC curves for the Normal, Reduced, and Tightened Sampling Plans are provided in Figures C-2 through C-16. Certain sampling plan selection criteria provide additional confidence in the acceptability of a critical characteristic than would be evident by just considering the OC curve risk factors. An example would be a satisfactory supplier product acceptance history.

Although OC curves were prepared for selective small lot sizes, the quality of submitted lots versus P<sub>a</sub> is really a set of discrete points. For example, a lot of five items could only have lot percent defectives of 0%, 20%, 40%, 60%, 80%, or 100%.

When evaluating the OC curves for small lots, it is also important to consider how small lots of CGIs are typically supplied. Most CGIs are manufactured in large production lots. Assume a production line is producing identical items with a 5% defective process average. Therefore, on the average, 5 out of 100 items will be defective. If a small lot of five items were purchased and the distribution of the defectives in the production lot were random, then there would only be a 0.23 probability of receiving a lot with one or more defectives. Thus, in this particular case, there would only be a 0.23 probability of having defectives in the submitted lot prior to performing any acceptance sampling. If, instead, the defectives were grouped together consecutively in the production lot, then typically 18 out of 20 lots of five would have no defectives. At least one of the two remaining lots would have a high probability of rejection because of the large number of defectives in the lot.

Another important consideration from a manufacturing standpoint is how defective items are produced. If a product process is out of control, the result tends to be a systematic rather than random problem. For example, if a machine starts producing out-of-tolerance parts because of tool wear, a large percentage—if not all of the manufactured items on the production run—would typically be nonconforming. Another example could involve a heat treatment furnace that is out of calibration by 50 degrees Fahrenheit (°F). The effect of the improper heat treatment might similarly impact the physical properties of the complete production run. These nonconforming production runs would continue until the product manufacturer recognizes and corrects the problem. Therefore, when receiving identical products from a given product manufacturer, a nonconforming critical characteristic will often be present in a significant portion of the submitted lot. Such lots will have a small probability of acceptance.

# C.2 Normal Sampling Plan

The Normal Sampling Plan is intended to provide a reasonable sample size to assure critical characteristic conformance when there are no overriding selection factors that would justify a less stringent or more stringent sampling plan.

Up to lot sizes of 50, the hypergeometric distribution was used to determine the Normal Sampling Plan's ability to detect defects and to establish sample sizes. Most recognized sampling plans like MIL-STD-105E were developed using the Poisson or Binomial distributions to establish probabilities of acceptance. For small lots, the hypergeometric distribution is the proper way of calculating probabilities. The hypergeometric distribution recognizes that once an item is selected as part of the sample, it is not replaced in the lot before the next item is taken. The hypergeometric equation also factors in lot size, which has an effect for small lots. The Poisson and Binomial distributions assume an infinite lot.

The Normal Sampling Plan provides a level of protection equal to or better than a MIL-STD-105E AQL of 4.0 for lot sizes up to 50. Table C-1 provides a comparison of sample sizes between the Normal Sampling Plan and MIL-STD-105E AQLs 1.0, 1.5, 2.5, and 4.0, up to a lot size of 50.

LOT SIZE	<u>AQL 1.0</u>	AOL 1.5	AQL 2.5	<u>AQL 4.0</u>	NORMAL PLAN
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\13\\13\\13\\13\\13\\13\\13\\13\\13\\13\\13\\13\\$	1 2 3 4 5 6 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	1 2 3 4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	1 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	1 2 2 3 3 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 5 5
LOT SIZE	<u>AQL 1.0</u>	AOL 1.5	AQL 2.5	<u>AQL 4.0</u>	PLAN B
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50	13         13	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	*13 13 13 13 13 13 13 13 13 13 13 13 13 1	7 7 7 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9

# Table C-1 Comparison of MIL-STD-105E Sampling Plans with Normal Sampling Plan

\*Sample size is larger than for AQL 1.5 and 2.5 because the AQL 4.0 has an Accept number of 1 and a Reject number of 2 for lot sizes of 26-50.

For lot sizes above 50, the Normal Sampling Plan is considerably better than an AQL of 4.0. As the sample size increases with lot size, both the AQL and LQ of the sampling plan improves. For lot sizes greater than 225, the sample size remains fixed at 32. No further increase in sampling is considered warranted for the Normal Sampling Plan. At

a sample size of 32, the AQL at a 95%  $P_a$  is 0.2%, and the LQ level at a 10% consumer's risk is 6.5%. The AQL and LQ remain essentially the same at a sample size of 32 irrespective of further increases in lot size.

The **Normal Sampling** Plan's increase in sample size with lot size has some similarity to MIL-STD-105E, General Inspection Level II, Normal Inspection, except that a progressive rather then quantum increase in sample sizes is employed.

OC curves for selective lots and corresponding sample sizes are provided in Figures C-2 through C-6. The hypergeometric equation was used to calculate probabilities of acceptance.









Figure C-3 Operating Characteristic Curves for the Normal Sampling Plan







Figure C-5 Operating Characteristic Curves for the Normal Sampling Plan



Figure C-6 Operating Characteristic Curves for the Normal Sampling Plan

# C.3 Reduced and Tightened Sampling Plans

The Reduced and Tightened Sampling Plans were developed based on guidance provided in MIL-STD-105E, which provides three levels of inspection based on the degree of discrimination desired [19]. Level I can be used when less discrimination is needed. Level II is the normal plan. Level III can be used when more discrimination is needed. Feigenbaum describes that the Level I sample sizes were designed to require about 0.4 as much inspection as Level II. The Level III sample sizes were designed to require about 1.6 as much inspection as Level II. The Reduced and Tightened Sampling Plans were similarly designed to average approximately 0.5 and 1.5, respectively, the amount of inspection as the Normal Sampling Plan.

Reduced Sampling Plan OC curves for selective lots and the corresponding sample sizes are provided in Figure C-7 through C-11. Up to a lot size of 50, the hypergeometric equation was used to calculate probabilities of acceptance. For lots greater than 50, the Binomial distribution was utilized. For lots greater than 225, the sample size remains fixed at 16. At a sample size of 16, the AQL at a 95% P<sub>a</sub> is 0.3%, and the LQ level at a 10% consumer's risk is 13.4%.





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Figure C-8 Operating Characteristic Curves for the Reduced Sampling Plan







Figure C-10 Operating Characteristic Curves for the Reduced Sampling Plan





Tightened Sampling Plan OC curves for selective lots and the corresponding sample sizes are provided in Figure C-12 through C-16. The hypergeometric equation was used to calculate probabilities of acceptance. For lots greater than 225, the sample size remains fixed at 48. At a sample size of 48, the AQL at a 95%  $P_a$  is 0.1%, and the LQ level at a 10% consumer's risk is 4.2%. At this sample size, the AQL and LQ values will remain essentially the same irrespective of lot size increases.

Section 2.4.3 provides guidance on when it is appropriate to the use the Reduced or Tightened Sampling Plans.







Figure C-13 Operating Characteristic Curves for the Tightened Sampling Plan









Figure C-15 Operating Characteristic Curves for the Tightened Sampling Plan



Figure C-16 Operating Characteristic Curves for the Tightened Sampling Plan