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ACCEPTANCE SAMPLING METHODS FOR SAMPLE RESULTS VERIFICATION

Carole A. Jesse

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DOE Contract
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Published June 1993

**IDAHO NATIONAL ENGINEERING LABORATORY
EG&G IDAHO, INC.
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ACCEPTANCE SAMPLING METHODS FOR SAMPLE RESULTS VERIFICATION

June 1993

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ABSTRACT

This report proposes a statistical sampling method for use during the sample results verification portion of the validation of data packages. In particular, this method was derived specifically for the validation of data packages for metals target analyte analysis performed under United States Environmental Protection Agency Contract Laboratory Program protocols, where sample results verification can be quite time consuming. The purpose of such a statistical method is to provide options in addition to the "all or nothing" options that currently exist for sample results verification. The proposed method allows the amount of data validated during the sample results verification process to be based on a balance between risks and the cost of inspection.

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ACCEPTANCE SAMPLING METHODS FOR SAMPLE RESULTS VERIFICATION

1. INTRODUCTION

This report describes a statistical sampling method for implementation in the Sample Results Verification (SRV) portion of data validation which is performed by the Sample Management Office (SMO). In particular, this method was derived specifically for the validation of data packages for metals target analyte analysis performed under United States Environmental Protection Agency Contract Laboratory Program (CLP) protocols, where SRV can be quite time consuming. The purpose of such a statistical method is to provide options in addition to the "all or nothing" options that currently exist for SRV. The proposed method allows the amount of data validated during the SRV process to be based on a balance between risks and the cost of inspection.

The report begins with a discussion of the data validation process. Then Section 3 introduces the concept of acceptance sampling and illustrates how it applies to SRV. The specifics of the acceptance sampling plans are covered in Sections 4 and 5, and Appendix A. A discussion of recommendations can be found in Section 6. The technical details of the mathematical statistics are left to Appendix B and C, for those readers who may be interested.

To avoid massive confusion between the two distinct uses of the word *sample* in this report, the following convention will be used throughout:

Sample:

The use of the word *sample* will be the same as that employed by the SMO. In other words, *sample* will be used when referring to a portion of material to be analyzed that is contained in a single or multiple containers and identified by a unique sample number.

Statistical Sample:

The term *statistical sample* will be used when referring to a subset of distinct units which have been drawn from a population. For this report statistical sample will always refer to a subset of the reported values contained in a data package.

2. DATA VALIDATION

Data validation is the process of evaluating the quality and reliability of data produced during laboratory analyses. The SMO is responsible for the validation of data packages that are generated under CLP protocols.

The management of data, from the identification of initial need to the data delivery, occurs in the following way. A project manager determines that existing data for a given operable unit is inadequate to answer their questions regarding risk to human health or the environment. A Sampling and Analysis Plan is then developed which specifies how many samples are to be collected, and how they are to be gathered and analyzed for particular analytes in question. The finite, predetermined number of samples required for the project are collected over a given time period from a particular site. The term case refers to the entire collection of samples needed for the project.

As the samples from one case are submitted to the contract laboratory they are grouped into *sample delivery groups*. A sample delivery group (SDG) consists of 20 or fewer samples of the same matrix (i.e. soil or water) from one case sent to the contract laboratory, over a 14 day period, for the same analysis. A case will consist of one or more SDGs. The *data package* which is generated on an SDG by the contract laboratory will include the analysis results of all samples in the SDG including field samples, dilutions, reanalyses, blanks, spikes, duplicates, and laboratory control samples.

The data package associated with an SDG includes, for each sample, a form (Form 1) containing the analyte concentration values from the analysis of the sample. An analyte concentration value contained on a Form 1 is here after referred to as a *reported value*. For the remainder of this report, the term sample delivery group (SDG), when used, will refer specifically to the entire collection of reported values contained in a data package.

The extent of data validation required for a case is usually determined by the project manager, based on the intended use of the data. Currently the four

data validation levels are A, B, C, and X, as defined in SMO-SOP-12.1.1. Essentially the data validation level determines the extent of validation to be done on the data packages comprising the project manager's case. There are many parts to the complicated process of data validation and they are dictated by the data validation level.

The objective of the SRV portion of data validation is to ensure that the reported values accurately represent those values generated in the laboratory for a particular sample. In the case of inorganic analyses on soil/sediment matrix samples, there is extensive transformation of the raw data in order to arrive at the reported values on the Form 1's. SRV consists of verifying this transformation process for an individual reported value as well as comparing the reported value to the calibration range and instrument detection limit. SRV can be a substantial part of data validation when the samples are of a soil or sediment matrix submitted for inorganic analysis.

For a Level A data validation, which is the most stringent validation level, SRV is required on all reported values in the data package. Data validation levels B, C, and X, do not require any SRV, and in fact parts of the SRV are impossible to perform for data validation level X due to the unavailability of raw data. The main purpose of this report is to provide the project manager and/or the validator with other options beyond the "all" (level A) or "nothing" (levels B and C) requirements that currently exist for SRV. The statistical method used to develop these other options is based on acceptance sampling as discussed in the next section.

3. ACCEPTANCE SAMPLING

3.1 GENERAL

Acceptance Sampling is a quality control method for determining the acceptability of a batch of manufactured product after it has been produced. In this context the term *batch* refers to a collection of manufactured product made within a specified time frame under like conditions. The producer of the manufactured product (the *Producer*) must assure the buyer (the *Consumer*) that the batch meets or exceeds the consumer's requirements. An individual unit of product (*unit*) which does not meet the consumer's requirements is considered *nonconforming*, otherwise it is considered to be a *conforming* unit. One measure of the quality of a batch is the fraction of nonconforming units, expressed as a percentage (here after referred to as the *fraction nonconforming* and denoted by p). Since it is very difficult to eliminate all process variation, the fraction nonconforming will vary from one batch to the next. The consumer wants the fraction nonconforming to be controlled but is usually willing to assign a *maximum allowable fraction nonconforming* that they are willing to tolerate.

One-hundred percent inspection with rectification is an inspection procedure where all the units in the batch are inspected and nonconforming units are replaced with conforming ones, thus guaranteeing the fraction nonconforming to be zero. In many instances one-hundred percent inspection is impractical since the cost of inspecting the product can be high and/or the inspection process may actually destroy the product (e.g. tensile testing). When these circumstances exist, only a subset (*statistical sample*) of the batch is inspected. The results from inspecting the statistical sample are then used to infer the nature of the entire batch. Acceptance sampling methods encompass this type of inspection procedure where statistical sampling of the batch is employed.

In the application of acceptance sampling to data validation, a single SDG represents a batch and the unit of product to be inspected is an individual reported value. The Producer is the laboratory generating the SDGs, and the Consumer is the project manager or the ultimate user of the reported values.

During SRV a reported value is checked for the nonconformities that are listed in a standard operating procedure (SMO-SOP-12.1.5, Section X). When a reported value exhibits one or more of these nonconformities it is considered nonconforming. Attempts are made to correct the problem if possible, otherwise the reported value may be qualified by the validator.

One-hundred percent inspection is the requirement for SRV on a level A validation. To move from one-hundred percent inspection to an acceptance sampling approach to SRV it is necessary to understand the risks involved. The risks associated with acceptance sampling methods are discussed in the next section.

3.2 CONSUMER'S AND PRODUCER'S RISKS

One-hundred percent inspection does not involve statistical sampling and therefore has no potential for either falsely accepting or falsely rejecting a batch. The previous statement assumes the inspection process itself is perfect (conforming units are always deemed good, and nonconforming units are always deemed bad), and this is also an underlying assumption used throughout this report. When the outcome of inspecting a statistical sample is used to infer the nature of an entire batch the potential for erroneous decisions increases, therefore the risks of false acceptance and false rejection become non-zero.

False acceptance of an SDG means that it has been deemed acceptable when in fact the proportion of nonconforming reported values is worse than the maximum allowable that the project manager will tolerate. The likelihood, or probability of false acceptance associated with an acceptance sampling plan is called the *Consumer's Risk*. Similarly, *false rejection* of an SDG means that it has been deemed unacceptable and has been rejected, when in fact the proportion of nonconforming reported values is no worse than the maximum allowable defined by the project manager. The probability of false rejection associated with an acceptance sampling plan is called the *Producer's Risk*. Both Consumer's and

Producer's Risks are expressed as percentages in this report. An incremental decrease in either the Consumer's or Producer's Risk typically requires an increase in the size of the statistical sample or an increase in the other risk.

In terms of SRV, the project manager may be willing to tolerate a maximum allowable fraction nonconforming, denoted by p_1 , in the SDGs of a case. This maximum allowable fraction nonconforming should be dictated by the criticality of the data and its end use, similar to the data validation level. If an SDG is rejected based on a statistical sample, the resulting action taken by the validator is to inspect all the reported values in the SDG. By doing so the validator will know if false rejection has taken place. If false rejection has occurred it means the SDG was rejected when in fact the fraction nonconforming is no worse than p_1 . The consequence of false rejection is the unnecessary cost incurred by the project manager from the resulting one-hundred percent inspection. Thus, the application of acceptance sampling to data validation is unusual in that the project manager, the Consumer, is directly affected by the Producer's Risk. The project manager will want an acceptance sampling plan with a small Producer's Risk. It is worth noting that while small Producer's Risk helps avoid unnecessary one-hundred percent inspection it also requires a larger statistical sample size.

Contrary to the case of false rejection, the validator will not know if false acceptance has occurred. Careful thought should be given to the ramifications of false acceptance of an SDG, i.e., what are the consequences of accepting an SDG with a fraction nonconforming worse than p_1 ? The consequences of false acceptance include the potential for incorrect decisions, based on the reported values, regarding the risks to human health and the environment caused by the contaminant levels present at a site. These consequences can be great. The project manager will want an acceptance sampling plan where the likelihood of false acceptance is low (small Consumer's Risk) for the chosen p_1 .

There are many different types of acceptance sampling plans. The type of acceptance sampling plan alluded to in the previous discussion, one statistical sample drawn from the batch for inference purposes, is called a single sampling

plan. Other types of acceptance sampling plans may involve two (double sampling) or more (multiple sampling) statistical samples. This report deals only with the development of single and double sampling plans for the SRV application.

4. SINGLE SAMPLING PLANS

4.1 INTRODUCTION

To determine the acceptability of a batch using a single sampling plan for attributes, a statistical sample is randomly drawn from the batch and inspected. If the number of nonconforming units in the statistical sample, denoted by X , exceeds a predetermined number, the batch is rejected, otherwise it is accepted. The number of units in the batch is denoted by N and the number of units inspected (statistical sample size) is denoted by n . The predetermined number, corresponding to the maximum number of nonconforming units that are acceptable in the statistical sample, is denoted by Ac and is called the acceptance criterion. Since rejection of the batch occurs if the number of nonconforming units in the statistical sample is $Ac+1$ or more, the rejection criterion is denoted by $Re = Ac+1$. A single sampling plan is completely specified by n and Ac .

4.2 THE SINGLE SAMPLING PLANS FOR SAMPLE RESULTS VERIFICATION

Appendix A contains tables of single sampling plans for the validation of SDGs through the SRV process. Each table is associated with a specific value of the maximum allowable fraction nonconforming, denoted by p_1 , to be chosen by the project manager. Tables 1, 2, and 3 are based on a p_1 of 5%, 10%, and 20%, respectively.

Each table in Appendix A has six columns. The first column gives the SDG size (N). An individual sample delivery group submitted for metals target analyte analysis will contain between 1 and 20 samples, each analyzed for 23 analytes (24 if cyanide is included, which is rare). As a result, the number of reported values to be validated in a SDG runs between 23 and 460 by increments of 23, i.e., $N=23, 46, 69, \dots, 460$. The second and third columns provide the statistical sample size (n) and acceptance criterion (Ac), respectively, of the single sampling plan corresponding to the SDG size.

The calculations of the Consumer's and Producer's Risks (fourth and fifth column, respectively) associated with a particular single sampling plan are based on p_1 , N , n , and Ac . The mathematical statistics necessary for the calculation of Consumer's and Producer's Risks for the single sampling plans are discussed in Appendix B. However, a less detailed discussion is warranted at this point and is provided in the next two paragraphs.

In Section 3.2 the Consumer's Risk is defined as the probability of accepting a bad batch. In the context of this report, a "bad batch" is defined as an SDG with a fraction nonconforming (p) greater than the maximum allowable fraction nonconforming (p_1). The probability of accepting a bad batch is at a maximum for the first p which is greater than p_1 . The Consumer's Risks given in the fourth column of the tables in Appendix A correspond to this maximum.

The Producer's Risk (probability of rejecting a good batch), provided in the fifth column of the tables in Appendix A, is not the maximum possible for the given plans. A "good batch" is defined as an SDG with a fraction nonconforming (p) which is, at most, equal to the maximum allowable fraction nonconforming (p_1). The maximum Producer's Risk occurs when p is equal to p_1 , but under this condition the maximum Producer's Risk is approximately equal to one minus the maximum Consumer's Risk. Since these two maximized risks sum to one, as one risk decreases the other risk must increase, and it is impossible to simultaneously control both of them. Producer's Risk can also be evaluated for any p which is less than p_1 . The Producer's Risks of Appendix A correspond to the probability of rejecting an SDG whose fraction nonconforming is approximately half of the maximum allowable fraction nonconforming, i.e., Producer's Risk is evaluated for $p \approx 0.5 * p_1$. The decision to evaluate Producer's Risk at one half of the maximum allowable fraction nonconforming is based on engineering judgement. Producer's Risk, evaluated this way for a particular sampling plan, provides the likelihood of rejecting an SDG whose number of nonconforming reported values is actually very acceptable.

The last column of the tables in Appendix A corresponds to the plan's sampling fraction (n/N expressed in percent). The sampling fraction gives some indication of the potential cost reduction associated with using the single

sampling plan. It is important to note the sampling fraction reflects the potential cost reduction that one could expect over time, provided the contract laboratory is performing well relative to p_1 (when $p \ll p_1$). In other word, as the actual fraction nonconforming increases, the overall probability of rejection of the SDGs will increase, thus subsequent one-hundred percent inspection is more likely, thereby increasing the cost of inspection.

4.3 THE ASSUMPTIONS ASSOCIATED WITH THE SINGLE SAMPLING PLANS

All of the single sampling plans provided in Appendix A were generated under the following assumptions, which were established based on discussions with the SMO:

Given p_1 and N ,

- 1) Consumer's and Producer's Risks, denoted by α and β respectively, are equally important from the perspective of the project manager and should be at most 20%, and
- 2) nonconformities occur randomly in the SDG
- 3) all analytes and/or samples are of equal importance to the project manager

The first assumption essentially says, find an acceptance sampling plan such that we will accept SDGs with a fraction nonconforming which is approximately half of p_1 about 80% of the time, and we will reject SDGs with a fraction nonconforming that is slightly more than p_1 about 80% of the time. An acceptance sampling plan meeting these requirements is called an 80-80 plan. All of the single sampling plans in Appendix A are at least 80-80 plans.

The requirement of randomly occurring nonconformities is the second assumption. For the discussion of this assumption refer to Figures 1 through 4. In viewing the figures consider an SDG containing four samples, each analyzed for

four particular analytes. The reported values associated with this SDG can be thought of as elements of a matrix where the row of the matrix corresponds to the sample (S_i) and the column of the matrix corresponds to the analyte (A_j), as depicted in the figures. Figure 1 depicts a situation where the nonconforming reported values, denoted with an X, occur randomly.

	A_1	A_2	A_3	A_4
S_1	X			
S_2			X	
S_3		X		
S_4				X

Figure 1. Randomly occurring nonconforming reported values.

	A_1	A_2	A_3	A_4
S_1				
S_2	X	X	X	X
S_3				
S_4				

Figure 2. Nonconforming reported values correlated with samples.

	A_1	A_2	A_3	A_4
S_1			X	
S_2			X	
S_3			X	
S_4			X	

Figure 3. Nonconforming reported values correlated with analytes.

	A_1	A_2	A_3	A_4
S_1				
S_2				
S_3			X	X
S_4			X	X

Figure 4. Nonconforming reported values correlated with samples and analytes.

Figure 2 depicts a different situation, one where the nonconforming reported values are correlated with the samples. The situation depicted in Figure 2 could arise, for example, if the % solids for Sample 2 was computed incorrectly, thereby affecting all the reported values for that sample.

The situation depicted in Figure 3 is one where the nonconforming reported values are correlated with the analytes. In particular, all the Analyte 3 reported values are nonconforming. This situation could arise, for example, if the samples were analyzed for the wrong set of analytes.

Finally, Figure 4 depicts a situation that is a combination of the previous two scenarios, i.e., the nonconforming reported values are correlated with both the analyte and the sample. Use of the wrong dilution factor could generate an SDG of this nature.

If patterns, such as those depicted in Figures 2 - 4, are present in an SDG, then the true fraction nonconforming will be estimated properly provided the statistical sample of size n (reported values) is randomly selected from among all N sample/analyte combinations. If these sorts of patterns can be screened prior to SRV then alternate statistical sampling techniques could be employed. For instance, in performing the SRV it is most efficient for the validator to inspect reported values in a systematic way, i.e., inspecting all reported values for a particular sample before moving on to the next sample. If it is reasonable to assume that nonconforming reported values occur randomly in the SDG (no patterns), then the statistical sample size n given in the tables of Appendix A could be split into sets of 23 and the SRV inspection process could be performed by randomly selecting $n'=n/23$ samples and performing SRV on all the reported values for the n' samples.

In the examples depicted by the figures the true fraction nonconforming is 25% ($4/16 \times 100\%$), regardless of which scenario exists. Suppose that the acceptance sampling plan for this SDG specified a maximum allowable fraction nonconforming of 20% ($p_1 = 20\%$), with a statistical sample size of four ($n=4$), and an acceptance criterion of zero ($Ac = 0$). The proposed n' method described above would specify that one sample ($n' = n/4$) be randomly selected to receive SRV on all of its reported values. Note that the n' method would catch the 25% fraction nonconforming in Figures 1 and 3 regardless of which sample was selected. But in the scenarios described in Figures 2 and 4 false acceptance may occur depending on the sample chosen for inspection. Thus, it is crucial that there be no patterns present in order to justify the n' method on an SDG. Methods for screening these patterns will be addressed in a subsequent Standard Operating Procedure (SOP).

Lastly, the acceptance sampling plans contained in this report were generated under the assumption that all the reported values are equally important to the project manager (third assumption). In other words, no particular sample or analyte is of special importance in the SDG. Situations arise where this assumption may not be true. For example, a particular sample in the SDG may be of special interest to the project manager and subsequently they may want all the reported values for that sample to be processed through SRV. The acceptance sampling plans can still be applied to the remainder of the SDG. These type of situations will be addressed in more detail in a subsequent SOP.

In viewing the tables in Appendix A, notice that for a given p_1 , finding a single sampling plan which satisfies the first two assumptions becomes more difficult as N decreases. In the cases where N is small it was necessary to require 100% inspection since no sampling plans were found which met these two assumptions. However, this becomes less of a problem as p_1 increases.

For a given choice of N and p_1 there may be many single sampling plans which satisfy the above assumptions. To construct the tables in Appendix A, a computer program (written in the SAS® programming language, a commercial statistics software package), was used to generate a collection of single sampling plans satisfying the assumptions for each combination of p_1 and N . Each collection of plans was then trimmed down to one "best" plan for that p_1 and N , based on the relative size of α and β .

The use of these tables is best illustrated through an example. If the project manager requires an error rate of no more than 10% in the reported values associated with the SDGs in a case, then Table 2, with $p_1=10\%$, in Appendix A would be used. Once p_1 has been chosen, the validator performs the SRV on all the SDGs within the project manager's case according to the corresponding table. Suppose a data package arrives containing 414 reported values (18 samples). Table 2 specifies that 115 of the reported values (5 samples) should be randomly selected from the data package for the SRV process. If eight or fewer reported values in the statistical sample are nonconforming, then the SDG is accepted as good with respect to SRV. If the number of nonconforming reported values in the statistical sample exceeds eight, then the SDG is rejected as bad with respect

to SRV. When rejection occurs the validator will inspect all the remaining reported values in the data package. With this acceptance sampling plan ($N=414$, $n=115$, $Ac=8$) the likelihood of accepting an SDG with an error rate slightly worse than 10% is given by the Consumer's Risk of 12.3%. Similarly, the likelihood of rejecting an SDG with an error rate that is approximately 5% (half of 10%) is given by the Producer's Risk of 9.4%. This acceptance sampling plan requires inspection of about 28% of the reported values, provided the contract laboratory's quality level is significantly better than the 10% error rate.

5. DOUBLE SAMPLING PLANS

Double sampling may require that up to two statistical samples, one of size n_1 and a second of size n_2 , be taken for the sake of determining the acceptability of a batch. There are two sets of acceptance/rejection criteria at each stage of the statistical sampling. The advantage of double sampling is that, on the average, the sampling fraction may be less than the single sampling plan while maintaining the same risk levels, provided the Producer's actual quality level is significantly better than the maximum allowable fraction nonconforming. The disadvantage of double sampling is that it is a more complicated procedure than single sampling. Thus, even though there may be improvement in either the sampling fraction or the risks, the cost of implementation may be more for double sampling.

Double sampling plans were investigated as an acceptance sampling approach to SRV. The conclusion of the investigation is that it would not be cost effective to implement. However, double sampling is discussed and the efforts of the investigation are documented in Appendix C.

6. RECOMMENDATIONS

In implementing acceptance sampling to the SRV process the following recommendations are suggested.

- 1) Project managers and SMO personnel should be asked to review this document and the proposed single sampling plans for SRV with the following question in mind: Are the given levels of p_1 and Consumer's and Producer's Risks specified by these plans appropriate for their data validation needs? Other single sampling plans can be constructed based on new criteria if necessary.
- 2) The SMO should develop a cost model which relates the cost of validation to the number of reported values inspected, and other factors, then assess whether the single sampling plans are cost effective. If they are, determine what sort of reduction in average statistical sample size is required in order justify generating double sampling plans.
- 3) Consideration should be given to whether it is appropriate to assign one of the particular single sampling plans provided in this report ($p_1=5\%$, 10% , or 20%) to each of the data validation levels B and C. If not, determine the appropriate constraints for generating a single sampling plan for assignment to these data validation levels.

7. REFERENCES

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APPENDIX A
SINGLE SAMPLING PLAN TABLES

Table 1. Single sampling plan with $p_1 = 5\%$.^a

Size of SDG (N)	Statistical Sample Size (n)	Acceptance Number (Ac)	Consumer Risk ^b (α %)	Producer Risk ^c (β %)	Sampling Fraction (n/N %)
23 - 115	NA ^d	NA	NA	NA	100
138	92	3	16.8	0.0	67
161	92	3	12.8	10.4	57
184	115	4	12.1	9.2	63
207	115	4	15.8	5.1	56
230	115	4	18.7	10.6	50
253	161	5	5.3	6.4	64
276	161	5	7.0	13.5	58
299	161	5	8.5	8.9	54
322	161	6	16.0	3.3	50
345	161	6	17.9	5.9	47
368	161	6	19.6	4.0	44
391	184	6	8.9	12.5	47
414	184	6	9.9	9.3	44
437	184	6	10.9	12.4	42
460	184	6	9.2	15.5	40

a. This plan is based on the size of the SDG being validated, assumes a maximum allowable fraction nonconforming of 5%, and controls Consumer's and Producer's Risks at less than 20%.

b. The Consumer's Risk is evaluated for the smallest fraction nonconforming that is larger than 5%.

c. The Producer's Risks is evaluated for a fraction nonconforming that is approximately 2.5%.

d. NA = Not Applicable due to 100% inspection.

Table 2. Single sampling plan with $p_1 = 10\%$.^a

Size of SDG (N)	Statistical Sample Size (n)	Acceptance Number (Ac)	Consumer Risk ^b (α %)	Producer Risk ^c (β %)	Sampling Fraction (n/N %)
23 - 46	NA ^d	NA	NA	NA	100
69	46	3	16.1	0.0	67
92	69	5	6.6	0.0	75
115	69	5	14.5	4.3	60
138	69	5	19.9	5.8	50
161	69	5	17.8	6.5	43
184	92	6	7.2	8.4	50
207	92	6	9.3	9.0	44
230	92	6	8.4	15.2	40
253	92	6	10.0	14.7	36
276	92	6	11.3	14.3	33
299	92	6	12.6	14.0	31
322	92	6	11.4	13.8	29
345	92	6	12.5	13.5	27
368	92	6	13.4	13.3	25
391	92	6	12.4	16.5	24
414	115	8	12.3	9.4	28
437	115	8	13.2	9.2	26
460	115	8	12.2	9.1	25

a. This plan is based on the size of the SDG being validated, assumes a maximum allowable fraction nonconforming of 10%, and controls Consumer's and Producer's Risks at less than 20%.

b. The Consumer's Risk is evaluated for the smallest fraction nonconforming that is larger than 10%.

c. The Producer's Risks is evaluated for a fraction nonconforming that is approximately 5%.

d. NA = Not Applicable due to 100% inspection.

Table 3. Single sampling plan with $p_1 = 20\%$.^a

Size of SDG (N)	Statistical Sample Size (n)	Acceptance Number (Ac)	Consumer Risk ^b (α %)	Producer Risk ^c (β %)	Sampling Fraction (n/N %)
23	NA ^d	NA	NA	NA	100
46	23	3	14.2	17.3	50
69	46	6	3.8	5.0	67
92	46	6	6.0	7.9	50
115	46	6	7.1	14.5	40
138	46	6	10.0	13.7	33
161	46	6	10.0	13.2	29
184	46	6	11.9	12.7	25
207	46	6	11.7	15.5	22
230	46	6	11.5	14.8	20
253	46	6	12.8	14.3	18
276	46	6	12.5	16.2	17
299	46	6	13.6	15.7	15
322	46	6	13.3	15.2	14
345	46	6	13.0	16.6	13
368	46	6	13.8	16.2	13
391	69	9	6.7	12.5	18
414	69	9	7.3	12.2	17
437	69	9	7.1	13.4	16
460	69	9	7.0	13.0	15

a. This plan is based on the size of the SDG being validated, assumes a maximum allowable fraction nonconforming of 20%, and controls Consumer's and Producer's Risks at less than 20%.

b. The Consumer's Risk is evaluated for the smallest fraction nonconforming that is larger than 20%.

c. The Producer's Risks is evaluated for a fraction nonconforming that is approximately 10%.

d. NA = Not Applicable due to 100% inspection.

APPENDIX B
MATHEMATICAL STATISTICS OF THE SINGLE SAMPLING PLANS

B-1 NOTATION

The following conventions in notation will be used throughout Appendix B:

N = batch size, the number of units contained in the batch

k = the actual number of nonconforming units contained in the batch

p_1 = the maximum allowable fraction nonconforming in the batch, specified as either a fraction or a percentage

d_1 = the maximum allowable number of nonconforming units in the batch, based on p_1 (d_1 is the largest integer such that $d_1/N \leq p_1$)

n = statistical sample size, the number of units to be randomly selected from the batch for inspection

X = the number of nonconforming units in the statistical sample

Ac = maximum allowable number of nonconforming units in the statistical sample (if $X \leq Ac$, then the batch is accepted; if $X > Ac$, then the batch is rejected)

α = probability of falsely accepting a batch, also called Consumer's Risk

= $P(\text{accept the batch given that it is "bad"})$

= $P(X \leq Ac \mid k > d_1)$

β = probability of falsely rejecting a batch, also called Producer's Risk

= $P(\text{reject the batch given that it is "good"})$

= $P(X > Ac \mid k \leq d_1)$

p_2 = a fraction nonconforming which is no greater than p_1 , expressed as either a fraction or a percentage

d_2 = the number of nonconforming units most closely defined by p_2 , i.e., $p_2 * N$ rounded to the nearest integer

B-2 THE HYPERGEOMETRIC PROBABILITY DISTRIBUTION

Given a batch of size N which contains k nonconforming units and a statistical sample size of n , the number of nonconforming units in the statistical sample (X) is distributed as a hypergeometric random variable. The probability that the statistical sample will contain exactly r nonconforming units is denoted by $h(N, n, k, r)$ and is defined by the Hypergeometric Probability Distribution:

$$P(X = r) = h(N, n, k, r) = \frac{C(k, r) C(N-k, n-r)}{C(N, n)} \quad \text{for } r = 0, 1, 2, \dots, k$$

$$\text{where } C(a, b) = \frac{a!}{(a-b)! b!}$$

and $a!$ denotes the product $a(a-1)(a-2)\dots(2)(1)$.

The probability that the statistical sample will contain at most r nonconforming units is denoted by $H(N, n, k, r)$ and is defined by the Cumulative Hypergeometric Probability Distribution:

$$P(X \leq r) = H(N, n, k, r) = \sum_{i=0}^r P(X = i) = \sum_{i=0}^r \frac{C(k, i) C(N-k, n-i)}{C(N, n)}$$

B-3 DETERMINATION OF CONSUMER'S AND PRODUCER'S RISKS

The determination of the Consumer's and Producer's Risks associated with a particular single sampling plan is based on N , n , Ac , p_1 , and p_2 , as defined in the previous notation section.

B-3.1 DETERMINATION OF CONSUMER'S RISK

To determine the value of Consumer's Risk associated with a particular single sampling plan the Cumulative Hypergeometric Probability Distribution is employed. As defined in Section 3.2, Consumer's Risk is the probability of falsely accepting a batch based on the statistical sample results. When false acceptance occurs it means that a batch has been accepted when the fraction nonconforming is actually worse than what the Consumer is willing to tolerate.

The maximum allowable fraction nonconforming that the Consumer is willing to tolerate is denoted by p_1 . Consumer's Risk is at a maximum when the number of nonconforming units in the batch is one more than the maximum allowable number of nonconforming units, i.e., for $k = d_1 + 1$.

The maximized Consumer's Risk, α , is provided in the tables of Appendix A, and is calculated as follows:

$$\alpha = P(X \leq Ac, \text{ given } k=d_1+1)$$

$$= H(N, n, d_1+1, Ac) = \sum_{i=0}^{Ac} \frac{C(d_1+1, i) C(N-(d_1+1), n-i)}{C(N, n)}$$

B-3.2 DETERMINATION OF PRODUCER'S RISK

The Cumulative Hypergeometric Probability Distribution is used in the calculation of the Producer's Risk associated with a single sampling plan. The Producer's Risk is the probability of falsely rejecting the batch based on the statistical sample results. When false rejection occurs it means that a batch had been rejected when the fraction nonconforming is actually no worse than what the Consumer is willing to tolerate.

The maximum allowable fraction nonconforming that the Consumer is willing to tolerate is denoted by p_1 . Producer's Risk is maximized for the case in which the true number of nonconforming units in the batch is equal to the maximum allowable, or when $k = d_1$. But it is frequently more desirable to evaluate the Producer's Risk when the fraction nonconforming is much better than p_1 , as this provides a perspective on the plan's propensity to discriminate against good batches. The decision as to which value of fraction nonconforming is to be used in the evaluation of Producer's Risk is somewhat arbitrary. The Producer's Risks associated with the single sampling plans provided in this report are calculated based on a fraction nonconforming which is approximately half of the maximum allowable, or $p_2 \approx 0.5 * p_1$. This is accomplished with $p_2 = d_2/N$, where d_2 is obtained by rounding $0.5 * p_1 * N$ to the nearest integer. Subsequently, Producer's Risk (β) is calculated as follows:

$$\beta = P(X > Ac, \text{ given } k=d_2) = 1 - P(X \leq Ac, \text{ given } k=d_2)$$

$$= 1 - H(N, n, d_2, Ac) = 1 - \sum_{i=0}^{Ac} \frac{C(d_2, i) C(N-d_2, n-i)}{C(N, n)}$$

APPENDIX C
MATHEMATICAL STATISTICS OF THE DOUBLE SAMPLING PLANS

C-1 NOTATION

The following conventions in notation will be used throughout Appendix C:

- N = batch size, the number of units contained in the batch
- k = the actual number of nonconforming units contained in the batch
- p_1 = the maximum allowable fraction nonconforming in the batch, specified as either a fraction or a percentage
- d_1 = the maximum allowable number of nonconforming units in the batch, based on p_1 (d_1 is the largest integer such that $d_1/N \leq p_1$)
- n_1 = statistical sample size for the first stage of acceptance sampling
- n_2 = statistical sample size for the second stage of acceptance sampling
- X_1 = the number of nonconforming units in the first statistical sample
- X_2 = the number of nonconforming units in the second statistical sample
- Ac_1 = acceptance criterion for the first statistical sample
(if $X_1 \leq Ac_1$, then the batch is accepted)
- Re_1 = rejection criterion for the first statistical sample
(if $X_1 \geq Re_1$, then the batch is rejected)
- Ac_2 = acceptance criterion for the second statistical sample
(if $(X_1 + X_2) \leq Ac_2$, then the batch is accepted, otherwise the batch is rejected)
- Re_2 = rejection criterion for the second statistical sample
(if $(X_1 + X_2) \geq Re_2$, then the batch is rejected, otherwise the batch is rejected) Note: $Re_2 = Ac_2 + 1$
- α = probability of falsely accepting a batch, also called Consumer's Risk
= $P(\text{accept the batch given that it is "bad"})$
- β = probability of falsely rejecting a batch, also called Producer's Risk
= $P(\text{reject the batch given that it is "good"})$
- p_2 = a fraction nonconforming which is no worse than p_1 , expressed as either a fraction or a percentage
- d_2 = the number of nonconforming units most closely defined by p_2 , i.e., $p_2 * N$ rounded to the nearest integer

C-2 INTRODUCTION TO DOUBLE SAMPLING

Double sampling may require that up to two statistical samples be taken for the sake of determining the acceptability of a batch. To determine the acceptability of a batch using a double sampling plan for attributes, a statistical sample is randomly drawn from the batch and inspected. If the number of nonconforming units in the first statistical sample (X_1) is less than or equal to a predetermined number (Ac_1), the batch is accepted. If the number of nonconforming units in the first statistical sample is Re_1 or more, the batch is rejected and all of the reported values are subjected to SRV. If the number of nonconforming units in the first statistical sample is between Ac_1 and Re_1 , another statistical sample is taken of size n_2 . Note, in double sampling the first stage acceptance number (Ac_1) and the first stage rejection number (Re_1) must differ by more than one, i.e., $Re_1 \geq Ac_1 + 2$. If they did not, then the sampling could never progress to the second stage and therefore the plan would essentially be a single sampling plan.

If a second statistical sample is needed, the number of nonconforming units in the second statistical sample (X_2) is combined with X_1 and the total is compared to a second (combined) acceptance criterion, Ac_2 . If the total number of nonconforming units in the two statistical samples exceeds Ac_2 the batch is rejected, otherwise it is accepted. A double sampling plan is completely specified by n_1 , Ac_1 , Re_1 , n_2 and Ac_2 .

The advantage of double sampling is that, on the average, the sampling fraction may be less than the single sampling plan while maintaining the same risk levels. In double sampling the final statistical sample size drawn from a batch will be equal to n_1 or n_1+n_2 , depending on the true quality level of the batch and the statistical sample obtained. An average statistical sample size can be computed based on the probabilities associated with accepting at the first stage and accepting at the second stage, given the actual quality level p . When the Producer has good quality level relative to p , the average statistical sample size will lean toward n_1 , which is typically less than the statistical sample size required for single sampling. The disadvantage of double sampling is that

it is a more complicated procedure than single sampling. Even though there may be improvement in either the sampling fraction or the risks, the cost of implementation may be more than for single sampling.

C-3 DOUBLE SAMPLING PLANS FOR SAMPLE RESULTS VERIFICATION

In generating double sampling plans for SRV it was decided to keep the risks approximately the same as those of the corresponding single sampling plan and try to reduce the sampling fraction.

For a given choice of N and p_1 there may be many double sampling plans which satisfy the 80-80 assumption that was used for the single sampling plans. The actual assumptions used for generating double sampling plans are more stringent in that the Consumer's and Producer's Risks should be at least as good as those afforded by the single sampling plan, and the average statistical sample size must be considerably less than the n of the single sampling plan for it to be cost effective.

In examining double sampling plans for the SRV application, a computer program was written (again in the SAS® programming language) which, for a given p_1 and N , would generate a collection of double sampling plans. Each collection was then searched for a best plan which would satisfy the stringent assumptions imposed by the single sampling plan. This process is very tedious and time consuming for the double sampling plans. For efficiency it was initially done under the 80-80 assumption, but not the multiple of 23 statistical sample size assumption. Additionally, during the early computer programming runs, it was assumed that cyanide was included in the metals target analyte analysis. The conditions that the computer program was run under were with $N=480$ with a p_1 of 20%, since these are conditions under which a comparable double sampling plan is most likely to be found. The double sampling plan that was generated under these conditions is provided below.

For $N=460$ and $p_1=20\%$, the single sampling plan given in Table 3 of Appendix A is:

n	Ac	Consumer's Risk	Producer's Risk
69	9	7.0%	13.0%

For $N=480$ and $p_1=20\%$, the best double sampling plan found through the above generation process is:

n_1	Ac_1	Re_1	n_2	Ac_2	Consumer's Risk	Producer's Risk	Average n
34	3	7	33	9	11.5	11.4	47

In comparing the above single and double sampling plans, attention must be given to whether the reduction in statistical sample size from 69 (single sampling) to an average statistical sample size of 47 (double sampling) significantly overrides the increase in the cost of implementation. This may be difficult to assess without information regarding the ease of use of the single sampling plans. It is recommended that no more be done with the generation of double sampling plans until this information can be provided. Intuitively it seems that very little is gained through the use of double sampling plans for this application.

The calculations of the Consumer's and Producer's Risks associated with a particular double sampling plan are based on p_1 , N , n_1 , Ac_1 , Re_1 , n_2 , and Ac_2 . The mathematical statistics necessary for these calculations are discussed next.

C-4 DETERMINATION OF CONSUMER'S AND PRODUCER'S RISKS

The determination of the Consumer's and Producer's Risks associated with a particular double sampling plan is more complicated than for single sampling plans because there are more parameters to the plan. For double sampling plans Consumer's and Producer's Risks are based on N , n_1 , n_2 , Ac_1 , Re_1 , Ac_2 , p_1 , and p_2 , as defined in the previous notation section.

Using the functional notation defined for the Hypergeometric Probability Distribution and the Cumulative Hypergeometric Probability Distribution defined in Appendix B-2, the overall probability of rejecting, $P(\text{reject})$, is derived as follows:

Let $REJECT1$ = reject at first stage
 $CONTIN1$ = continue at first stage
 $REJECT2$ = reject at second stage

Then

$$\begin{aligned} P(REJECT1) &= P(X_1 \geq Re_1, \text{ given } N, n_1, k) \\ &= 1 - P(X_1 \leq (Re_1 - 1), \text{ given } N, n_1, k) \\ &= 1 - H(N, n_1, k, Re_1 - 1) \end{aligned} \tag{Eq C-4.1}$$

and

$$\begin{aligned} P(REJECT2) &= P(CONTIN1 \text{ and } REJECT2) \\ &= P(CONTIN1) P(REJECT2, \text{ given } CONTIN1). \end{aligned}$$

There are $Re_1 - Ac_1 - 1$ ways to continue at the first stage, i.e., $X_1 = Ac_1 + 1, Ac_1 + 2, \dots$, or $Re_1 - 1$. Therefore $P(REJECT2)$ becomes:

$$\begin{aligned}
 P(REJECT2) &= \sum_{i=Ac_1+1}^{Re_1-1} P(X_1 = i, \text{ given } N, n_1, k) P(X_2 \geq Re_2 - i, \text{ given } N-n_1, n_2, k-i) \\
 &= \sum_{i=Ac_1+1}^{Re_1-1} P(X_1 = i, \text{ given } N, n_1, k) [1 - P(X_2 \leq Re_2 - i - 1, \text{ given } N-n_1, n_2, k-i)] \\
 &= \sum_{i=Ac_1+1}^{Re_1-1} h(N, n_1, k, i) [1 - H(N-n_1, n_2, k-i, Re_2 - i - 1)] \quad (\text{Eq C-4.2})
 \end{aligned}$$

And finally, the overall probability of rejection, given N, n_1, n_2 , and k , is derived by combining Eq C-4.1 and Eq C-4.2:

$$\begin{aligned}
 P(\text{reject}) &= P(REJECT1) + P(REJECT2) \\
 &= \{[1 - H(N, n_1, k, Re_1 - 1)] + \\
 &\quad \sum_{i=Ac_1+1}^{Re_1-1} h(N, n_1, k, i) [1 - H(N-n_1, n_2, k-i, Re_2 - i - 1)]\} \quad (\text{Eq C-4.3})
 \end{aligned}$$

C-4.1 DETERMINATION OF CONSUMER'S RISK

Consumer's Risk is determined by evaluating Eq C-4.3 for $k=d_1+1$, given N, n_1, n_2, Ac_1, Re_1 , and Ac_2 , and subtracting the result from one (since $1 - P(\text{reject}) = P(\text{accept})$).

C-4.2 DETERMINATION OF PRODUCER'S RISK

Producer's Risk is determined directly by evaluating Eq C-4.3 for $k=d_2$, given N , n_1 , n_2 , Ac_1 , Re_1 , and Ac_2 . For this report d_2 was calculated as $0.5 \cdot p_1 \cdot N$ rounded to the nearest integer, thereby making $p_2=d_2/N$ approximately half of p_1 .

END

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