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An American National Standard

Standard Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis¹

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1. Scope

- 1.1 This guide covers minimum considerations for sampling of seized drugs for qualitative and quantitative analysis.
- 1.2 This guide cannot replace knowledge, skill, or ability acquired through appropriate education, training, and experience and should be used in conjunction with sound professional judgment.
- 1.3 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 ASTM Standards:²

E105 Guide for Probability Sampling of Materials

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E141 Practice for Acceptance of Evidence Based on the Results of Probability Sampling

E1732 Terminology Relating to Forensic Science

E2329 Practice for Identification of Seized Drugs

E2334 Practice for Setting an Upper Confidence Bound for a Fraction or Number of Non-Conforming items, or a Rate of Occurrence for Non-Conformities, Using Attribute Data, When There is a Zero Response in the Sample

2.2 ISO Standards:³

10.1520/E2548-16.

ISO 3534-1 Statistics – Vocabulary and Symbols – Part 1: Probability and General Statistical Terms

ISO 3534-2 Statistics – Vocabulary and Symbols – Part 2: Statistical Quality Control

3. Significance and Use

- 3.1 This guide provides information for the sampling of seized-drug submissions.
- 3.2 The principal purpose of sampling in the context of this guide is to answer relevant questions about a population by examination of a portion of the population. For example:

What is the net weight of the population?

What portion of the units of a population can be said to contain a given drug at a given level of confidence?

3.3 By developing a sampling strategy and implementing appropriate sampling schemes, as illustrated in Fig. 1, a laboratory will minimize the total number of required analytical determinations, while ensuring that all relevant legal and scientific requirements are met.

4. Sampling Strategy

- 4.1 An appropriate sampling strategy is highly dependent on the purpose of the investigation, the customer's request, and the anticipated use of the results. Laws and legal practices form the foundation of most strategies and shall be taken into account when designing a sampling scheme. Therefore, specific sampling strategies are not defined in this guide.
- 4.2 The laboratory has the responsibility to develop its own strategies consistent with this guide. It is recommended that the following key points be addressed:
 - 4.2.1 Sampling may be statistical or non-statistical.

Note 1—For the purpose of this guide, the use of the term *statistical* is meant to include the notion of an approach that is probability-based.

4.2.1.1 In many cases, a non-statistical approach may suffice. The sampling plan shall provide an adequate basis for answering questions of applicable law. For example,

Is there a drug present in the population?

Are statutory enhancement levels satisfied by the analysis of a specified number of units?

4.2.1.2 If an inference about the whole population is to be drawn from a sample, then the plan shall be either statistically

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

Sampling Strategy – Based upon jurisdictional requirements

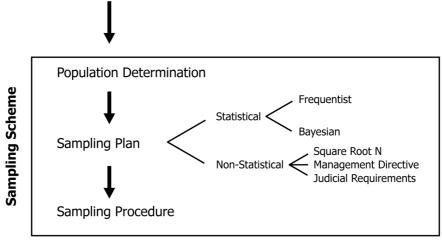


FIG. 1 Relationship of Various Levels Required in Sampling

based or have an appropriate statistical analysis completed and limits of the inference shall be documented.

4.2.2 Selected units shall be analyzed to meet Practice E2329 if statistical inferences are to be made about the whole population.

5. Sampling Scheme

- 5.1 The sampling scheme is an overall approach that includes population determination, selection of the sampling plan and procedure and, when appropriate, sample reduction prior to analysis (Fig. 2).
 - 5.2 Population Determination:
- 5.2.1 The population determination shall take into account all typical forms and quantities in which exhibits may appear.
- 5.2.2 A population can consist of a single unit or multiple units.
- 5.2.3 A multiple unit population shall consist of items that are similar in relevant visual characteristics (for example, size, color, shape, etc.).

SAMPLING PLAN

- 5.3 There are numerous sampling plans used in the forensic analysis of drugs that are applicable to single and multiple unit populations.
- 5.4 When a single unit or bulk population is to be analyzed, the issue of homogeneity shall be addressed within the sampling plan.
- 5.4.1 One sample is sufficient if the bulk material is homogeneous. Analysts can make bulk material homogeneous.
- 5.4.2 If the bulk material is not homogeneous, several samples from different locations may be necessary to ensure that the test results are representative of the bulk material and to avoid false negative results.
- 5.5 For a multiple unit population, the sampling plan may be statistical or non-statistical.
- 5.5.1 Statistical approaches are applicable when inferences are made about the whole population. For example:

The probability that a given percentage of the population contains the drug of interest or is positive for a given characteristic.

The total net weight of the population is to be extrapolated from the weight of a sample.

- 5.5.1.1 Published examples of statistical approaches involving general considerations:
 - (1) Practice E105.
 - (2) Practice **E141**.
 - (3) Terminology E1732.
 - (4) Guidelines on Representative Drug Sampling.⁴
 - (5) ISO 3534-1.
 - (6) ISO 3534-2.
- 5.5.1.2 Published examples of statistical approaches involving the hypergeometric, normal, and other distributions from a frequentist perspective:
 - (1) Frank, et al., Journal of Forensic Sciences.⁵
 - (2) Guidelines on Representative Drug Sampling.⁴
 - (3) Practice E2334.
 - (4) Practice E122.
- 5.5.1.3 Published examples of statistical approaches involving the hypergeometric, normal, and other distributions from a Bayesian perspective:
 - (1) Coulson, et al., Journal of Forensic Sciences.⁶
 - (2) Guidelines on Representative Drug Sampling.⁴
- 5.5.2 Non-statistical approaches are appropriate if no inference is to be made about the whole population.
 - 5.5.2.1 Published examples:
 - (1) The "square root method."

⁴ 2009 UNODC/ENFSI Guidelines on Representative Drug Sampling, European Network of Forensic Science Institutes (ENFSI), 2004, http://www.ENFSI.org.

⁵ Frank et al., "Representative Sampling of Drug Seizures in Multiple Containers," *Journal of Forensic Sciences*, Vol 36, No. 2, 1991, pp. 350–357.

⁶ Coulson et al., "How Many Samples from a Drug Seizure Need to Be Analyzed?," *Journal of Forensic Sciences*, Vol 46, No. 6, 2001, pp. 1456–1461.

⁷ Recommended Methods for Testing Opium, Morphine and Heroin: Manual for Use by National Drug Testing Laboratories, United Nations Office on Drugs and Crime, 1998.

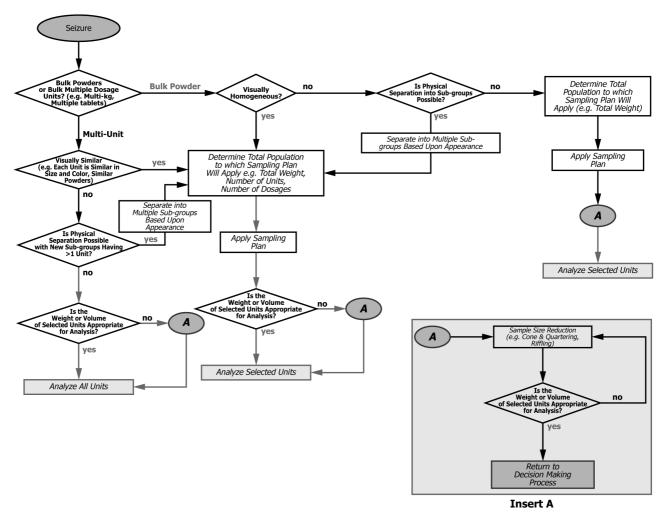


FIG. 2 Example of a Sampling Scheme—A Decision Flowchart

- (2) Methods listed in "Arbitrary Sampling" in *Guidelines* on Representative Drug Sampling.⁴
- 5.5.2.2 Selection of a single unit from a multiple unit population may be appropriate under certain circumstances (for example, management directives and legislative or judicial requirements, or both).
- 5.5.2.3 A non-statistical sampling approach may allow an inference about the population. If a single population has been randomly sampled, the data may allow an inference to be drawn by (1) determining and reporting a confidence interval for an inferred population parameter (for example: weight or tablet count); or by (2) retrospectively using the results in a statistical model and determining the resulting probabilities and level of confidence.
 - 5.6 Sampling Procedure:
- 5.6.1 Establish the procedure for selecting the number of units that will comprise a sample.
- 5.6.1.1 For non-statistical approaches, select a sample appropriate for the analytical objectives.
- 5.6.1.2 For statistical approaches, random sampling shall be conducted.

- 5.6.2 Select a Random Sample:
- 5.6.2.1 A random sample is one selected without bias and where each item has an equal chance of being selected. Computer generated random numbers or random number tables are commonly employed for such tasks and these should be included in the sampling plan.
- 5.6.2.2 Random sampling of items using random number tables may not be practical in all cases. In these instances, an alternate sampling plan shall be designed and documented to approach random selection. A practical solution involves a "black box" method, which refers to one that will prevent the sampler from consciously selecting a specific item from the population (that is, all units are placed in a box and the samples for testing are selected without bias). Random sampling is discussed in the following references:
 - (1) Practice E105.
 - (2) Frank, et al., Journal of Forensic Sciences.
 - (3) ISO 3534-1.
 - (4) ISO 3534-2.
- 5.7 Sample Reduction—Sample reduction may be applied in cases where the weight or volume of the selected units is too large for laboratory analysis (Fig. 2, insert A).

6. Analysis

- 6.1 Statistically Selected Sample(s)—In accordance with 4.2.2, it is recommended that each unit comprising the sample be analyzed to meet Practice E2329 if statistical inferences are to be made about the whole population.
- 6.2 *Non-statistically Selected Sample(s)*—Practice E2329 shall be applied to at least one unit of the sample.

7. Documentation

7.1 Inferences drawn from the application of the sampling plan and subsequent analyses shall be documented.

8. Reporting

8.1 Sampling information shall be included in reports.

- 8.1.1 Statistically Selected Sample(s)—Reporting statistical inferences for a population is acceptable when testing is performed on the statistically selected units as stated in 6.1 above. The language in the report must make it clear to the reader that the results are based on a probability-based sampling plan.
- 8.1.2 Non-Statistically Selected Sample(s)—The language in the report must make it clear to the reader that the results apply to only the tested units. For example, 2 of 100 bags were analyzed and found to contain Cocaine.

9. Keywords

9.1 analytical method; qualitative method; quantitative method; sampling; seized drug analytical method

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