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# **Procedures**

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Model Procedure for Sampling Inspection of Short Series of Lots

Procedure based on S-S-04



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## Model Procedure for Sampling Inspection of Short Series of Lots

#### 1.0 Scope

This model procedure applies to sampling inspection of short series of lots which meet the definition of homogeneity for the verification or reverification of measurement devices, in accordance with Annex B of Measurement Canada specification S-S-04.

This model procedure is based on specification S-S-04.

#### 2.0 Purpose

This model procedure provides instructions for the sampling inspection of short series of lots of homogeneous measurement devices by accredited service providers (ASP), in accordance with Annex B of Measurement Canada specification S-S-04.

Use of this procedure is optional. This model procedure is designed to provide assistance to ASPs who are responsible for developing, documenting and implementing policies and procedures for all activities involved in applying specifications related to sampling inspection.

#### 3.0 References

**3.1** ISO 2859-2:1985 - Sampling procedures for inspection by attributes - Part 2 - Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.

- **3.2** S-S-01 Specifications for Random Sampling and Randomization.
- **3.3** S-S-02 Measurement Uncertainty and Meter Conformity Evaluation Specifications.
- **3.4** S-S-03 Prerequisites to the Use of Sampling Inspection.
- **3.5** S-S-04 Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots.
- **3.6** Relevant Measurement Canada specification for measurement device verification and reverification.
- **3.7** S-01 Implementation Guide for the Application of Statistical Sampling Requirements.
- **3.8** ASP Approved Meter Inspection Procedures (see Appendix C).

[Insert other applicable references used by ASP]



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## 4.0 Definitions and Terms

[insert applicable definitions and terms used by ASP]

## 5.0 Apparatus

Software - Random Sampling Program.

[Insert other applicable apparatus used by ASP]

## 6.0 Procedure

## 6.1 Inspection Planning and Administration

**6.1.1** Include the following information when developing and documenting policies and procedures for sampling inspections:

- (a) roles and responsibilities;
- (b) quality records;
- (c) lot quality history (per homogeneous grouping);
- (d) handling, storage and preservation; and
- (e) clear links to existing procedures needed to carry out the procedure.

**6.1.2** Address the requirements of S-S-03 (reference 3.4) that are to be satisfied prior to the use of sampling methods.

6.1.3 Address the applicable requirements of S-S-03, as appropriate:

(a) For a new process, the process qualification requirements;

(b) For an existing process, the re-qualification requirements if there was a discontinuation or suspension of sampling inspection, or a significant change in the process;

(c) For an existing process, the historical evidence indicating a high quality process. If the process subsequently needs to be re-qualified, this option is not available; or

(d) For the transition from LQ of 3.15% to LQ of 8.0%, the process qualification requirements.

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- **6.1.4** Verify whether the following conditions exist:
  - (a) the production process quality is stable;
  - (b) the lots are submitted to inspection in the order of their production;
  - (c) the series of lots are homogeneous; and
  - (d) the lots are relatively similar in size.
- 6.1.5 Set up a lot tracking system for each sequence of homogeneous lots (Appendix D).
- **6.1.6** Determine the inspection option for performance characteristics (LQ of 3.15% or LQ of 8.0%).

6.1.7 Determine the sampling plan to be used for the series (i.e., sample size and acceptance number).

#### Recommendation

Operations initially start at the baseline LQ of 3.15% with an acceptance number of 1 or greater. Consideration should be given to the LQ of 8.0% (performance characteristics) or an acceptance number of zero once a consistently high level of quality is achieved. In addition, ASPs should become familiar with the re-qualification requirements of S-S-03 before undertaking more stringent sampling inspection options.

**6.1.8** Define the lot by documenting the technical parameters and the unique identification numbers of the meters. Access the lot number registry, assign the next unique identifier to the lot, and update the registry. Record these values on the inspection form (Appendix B).

## 6.2 Sample Selection

**6.2.1** Verify that all meters in the lot are homogeneous, as per the definition of homogeneity provided in the device verification specification (reference 3.6).

**6.2.2** Using the lot tacking system (Appendix D), determine the required action for the current lot.

**6.2.3** As applicable, prior to the re-start of sampling inspection, screen the lot to ensure the requirements of S-S-04, B.5.7 (reference 3.5) are met; once completed go to step 6.2.4.

**Note:** Typically, the sequence for a series of lots is as follows:

- Lot # 1 not accepted
- Lot # 2 screened and found satisfactory
- Lot # 3 sampled using sample size n<sub>1</sub>

**6.2.4** Determine the sample size and acceptance number using the table in Appendix A. Record these values on the inspection form (Appendix B).

(a) for performance characteristics, utilize values for LQ of 3.15% or 8.0% as determined in step 6.1.7; and

(b) for non-performance characteristics, utilize corresponding values in Table B.3 of S-S-04 for inspection option 1 or 2 determined in step 6.1.7.

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**6.2.5** Record the auditing parameters of the random sampling software, including the seeds, lot size, sample size, sampling type, date, time, lot identifier and operator identifier on the inspection form.

**6.2.6** Physically identify the sample units from the lot listing using the authorized random sampling software specified in section 5, above.

**6.2.7** List the sample unit identification numbers on the inspection form.

#### 6.3 Sample Inspection

**6.3.1** Inspect each meter identified in step 6.2.6, in accordance with the authorized inspection procedure (reference 3.8 and Appendix C).

**6.3.2** For each performance measurement, determine the measurement uncertainty for the inspection conducted according to the authorized inspection procedure. Apply that value to the test value to determine the extended measurement result (corrected for calibration console errors).

**6.3.3** Record the inspection results for each meter on the inspection form (Appendix B), stating:

(a) all performance measurement results recorded to the nearest 0.01% (refer to the applicable approved inspection procedure to determine the required resolution); and

(b) all relevant attribute-type results as acceptable or unacceptable.

**6.3.4** Calculate the absolute values of all performance test results and then calculate the measure of absolute deviation from target (MADT) value for each meter and record this value on the inspection form.

#### 6.4 Lot Acceptance or Non-acceptance

**6.4.1** Classify each sample meter inspection as conforming, marginally conforming (type 1, type 2), non-performance nonconforming or performance nonconforming by comparing each inspection result from steps 6.3.3 and 6.3.4 to the Measurement Canada specification requirements (reference 3.6). Record the results on the inspection form (Appendix B).

**6.4.2** Determine if the meter is conforming, marginally conforming type 1, marginally conforming type 2, non-performance nonconforming or performance nonconforming. Record the results on the inspection form.

**6.4.3** Determine if a two-stage procedure is to be carried out for meters possessing performance results which include the compressed specification limit or the specification limit. Carry out the procedure according to the authorized inspection procedure (reference 3.8) and record the results on the inspection form. Proceed to step 6.3 if applicable.

**6.4.4** Segregate all nonconforming meters and marginally conforming meters from the conforming meters.

**6.4.5** Count the total number of marginally conforming units (type 1 and type 2), non-performance nonconforming units and performance nonconforming units and record this value on the inspection form.

**Note:** Use the cumulative count for the second lot onwards following the start or re-start of sampling inspection.

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**6.4.6** Compare the count from step 6.4.5 with the acceptance number from step 6.2.4. Classify the lot as acceptable if:

- (a) the result from step 6.4.5 is less than or equal to the acceptance number;
- (b) there are no performance nonconformities; and
- (c) there are no nonconformities due to non-compliance with the meter's notice of pattern approval.

**6.4.7** Ensure all sample meters meet the performance requirements for 100% inspection as specified in the Measurement Canada specification requirements. Segregate all nonconforming meters from the conforming meters.

6.4.8 Record the acceptance status of the lot on the inspection form.

**6.4.9** Update the lot tracking system (Appendix D).

**6.4.10** File the completed inspection form and all other relevant documentation in the quality records system.

#### 6.5 Disposition of Units and Lots

**6.5.1** If the lot is not accepted, determine if the meters are to be returned to the vendor, scrapped or repaired. If the unacceptable lot is to be resubmitted for sampling inspection, ensure the requirements of S-S-04, Annex B.5.4 and B.5.5 (reference 3.5) are met. If resubmitted, screen all meters to ensure all nonconforming meters are removed and the outgoing quantities do not exceed the proportion represented by the LQ value.

**6.5.2** Correct, dispose of or replace all nonconforming meters and marginally conforming meters identified in steps 6.4.4, 6.4.7 and 6.5.1, ensuring the outgoing quality requirements of MC specification requirements (reference 3.6) are met.

**6.5.3** Determine if the lot is acceptable. Apply a verification mark to each conforming sample meter and each meter in the uninspected portion of the lot unless it is visually evident that an uninspected meter is nonconforming. Apply step 6.4.4 if applicable.

6.5.4 Determine if the lot is not acceptable. Apply a verification mark to each conforming sample meter.

**6.5.5** Determine if nonconformities or defects discovered during the inspection process or through management review are of a nature which compromises, or potentially compromises, measurement accuracy, meter integrity or appropriate usage of the meter and it is determined that the cause of the nonconformity or defect may impact additional meters of the same or similar make, type or model. If this is the case, reject the lot and suspend sampling inspection.

#### 6.6 Reporting of Critical Nonconformities or Defects

Notify Measurement Canada promptly with full details if there are any findings or observations made in step 6.4.6 (c) or 6.5.5. Measurement Canada shall indicate the future action to be taken.

## 6.7 Corrective Action

**6.7.1** Determine if an unacceptable lot is to be inspected under sampling or 100% inspection. If the lot is to be sampled and the steps in section 6.5 have been followed, proceed to step 6.2.

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**6.7.2** Determine if additional lots are planned. If additional lots are planned, implement corrective action and determine whether process requalification is necessary. Proceed to step 6.1.

#### 6.8 Quality Records

Update relevant quality records such as lot tracking log, inspection records, non-conformance and correction action records, etc.

#### 7.0 Documentation

- 7.1 Appendix A Table of Lot Sizes, Sample Sizes and Acceptance Numbers
- 7.2 Appendix B Template for Meter Sampling Inspection Spreadsheet
- 7.3 Appendix C Meter Inspection Procedure
- 7.4 Appendix D Lot Tracking System

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## Appendix A - Table of Lot Sizes, Sample Sizes and Acceptance Numbers

Extract the relevant contents of Table B.1, B.2 and B.3 of S-S-04 and insert here for convenient reference.

## Appendix B - Template for Meter Sampling Inspection Spreadsheet

[Insert approved electronic forms and templates]

#### Appendix C - Meter Inspection Procedure

**C.1** ASP to obtain approval for the meter inspection procedure referred to in clause 3.8.

C.2 Ensure each meter inspection procedure includes the following steps:

(a) identify explicitly all quality characteristics to be inspected for the meter type in accordance with the authorized inspection procedure;

(b) create an electronic form and give explicit instructions for recording all administrative and technical parameters of the meters as well as related information (including procedures and software used), the quality characteristics (both performance and non-performance) to be inspected, and the inspection results for all of the quality characteristics, leaving provision for entering all information required to be documented under this model procedure; and

(c) record all performance results to the nearest 0.01% (with supporting test resolution from the reference standard) and give proper instruction to apply measurement uncertainty and to correct the results for intrinsic errors of the calibration console. Refer to the applicable approved inspection procedure to determine the required measurement resolution.

**C.3** Application of the instructions in the meter inspection procedure and those in the sampling inspection procedure should result in the form referred to in step C.2(b) being completely filled in.

## Appendix D - Lot Tracking System

Create an electronic filing system to track lot history. Retain for each lot all pertinent information including lot identification, date, lot size, sample size, acceptance number (i.e.  $Ac_1$ ,  $Ac_2$ ,  $Ac_3$ , Ac), number of marginally conforming and nonconforming observations (i.e. type 1 and type 2 marginally conforming units, number of non-performance nonconforming units, number of performance nonconforming units), lot status and future action.