Bulletin

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Implementation Guide for the Application of Statistical Sampling Requirements

1.0 Purpose

1.1 The purpose of this bulletin is to provide guidance on the interpretation and application of Measurement Canada's new Acceptance Sampling Plan, S-S-04. These guidelines are intended for use by Authorized Service Providers (ASPs) accredited to S-A-01 requirements, as well as Measurement Canada (MC) staff.

1.2 This Guide explains the terms used in the sampling plans and provides practical guidance on sampling inspection. The requirements in this bulletin have been formatted with numbering for ease of reference, and are not intended to be used as checklists for accreditation audit purposes.

2.0 References

2.1 The Acceptance Sampling Plan is detailed in the following documents:

(a) Bulletin S-02, Implementation Policy for the Application of Statistical Sampling Requirements

(b) S-S-01 – Specifications for the Generation of Pseudo-Random Samples

(c) S-S-02 – Measurement Uncertainty and Meter Conformity Evaluation Specifications

(d) S-S-03 – Prerequisites to the Use of Sampling Inspection

(e) S-S-04 – Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots

2.2 The sampling inspection requirements are based on international standards. Users are encouraged to refer to:

(a) ISO 2859-10

(b) ISO TR 8550

(c) ISO Guide to Uncertainty in Measurement (GUM)

3.0 Terminology

3.1 For the documents referenced in this Guide, the terms "production" and "presentation" are used interchangeably.

3.2 For the documents referenced in this Guide, the term "implemented", as applied to corrective action, means that corrective action has been identified and carried out but not necessarily validated.

3.3 The ISO standard uses the terms “device” and/or “item”. For the documents referenced in this bulletin, those terms refer to a meter.

3.4 Other Terms and Acronyms

ASP means, “Authorized Service Provider” (or an “Accredited Meter Verifier” (AMV))

ISO means, “International Organization for Standardization”

JWG means, “Joint Working Group”

LQ means, “limiting quality”

MADT means, “median absolute deviation from target”

Type A evaluation means, a method of evaluation of uncertainty by statistical analysis of a series of observations.

Type B evaluation means, a method of evaluation of uncertainty by means other than the statistical analysis of a series of observations.

4.0 Principles Governing Sampling Inspection and Plan Design

4.1 During the review process the Sampling Project JWG considered a number of national and international sampling plans to use as the foundation element in the development of this acceptance sampling plan. The base plan that was selected is the internationally accepted ISO 2859-2 plan. The design parameters associated with this plan were consistent with the level of conformity that the JWG wanted to achieve. That is generally described as a relative confidence level that a certain percentage of devices under test are conforming.

4.2 With the ISO plan, the design parameter assumed a consumer’s risk of 10% probability of non-acceptance of a lot. The various LQ tables that are contained in ISO 2859-2 and which form the basis of S-S-04 were based on that probability. During the review process, a check of the ISO 2859-2 tables revealed two inconsistencies. They are associated with the LQ = 2.0% table for lot size 51– 90 and the LQ = 3.15% table for lot size 51– 90. In both cases, the probability of non-acceptance of a lot is over the 10% probability design parameter that was defined by the JWG. As a consequence, the JWG reached unanimous consensus on the following options to address these inconsistencies:

(a) All users should use sample sizes associated with one of the larger lot sizes

(b) Alternatively, the following sample sizes/lot size combination can be used:

(i) For LQ = 2.0% and lot size 51 – 90, use sample size of 57 units

(ii) For LQ = 3.15% and lot size 51 – 90, use sample size of 48 units

The JWG has also recommended that this inconsistency be communicated to the ISO 2859-2 committee for final resolution.

5.0 Guidelines on S-S-02

5.1 General Guidelines for the Determination of Measurement Uncertainty in Conformity Assessment (S-S-02, section 4.1.1)

5.1.1 With reference to S-S-02, "Measurement Uncertainty and Meter Conformity Evaluation Specifications", and specifically S-S-02, section 4.1.1, the determination of measurement uncertainty typically involves the following generic steps:

(a) Identification of the potential sources of uncertainty

(b) Determination of standard uncertainty (u_s) for each component

(c) Determination of the relationship between the components (statement of the reduction equation)

(d) Identification and evaluation of covariance terms

(e) Determination of the sensitivity coefficients for each component and creation of a uncertainty budget table

(f) Combining the standard uncertainties and sensitivity coefficients to determined the combined uncertainty (u_c) in accordance with the ISO Guide to Uncertainty in Measurement (GUM)

(g) Determination of the expanded uncertainty (U)

5.1.2 Evidence should be provided in the statement of uncertainty indicating the completion of the items listed in 7.1.1.

5.2 General List of Measurement Uncertainty Contributors in Conformity Assessment (S-S-02, section 4.1.2)

With reference to section 4.1.2 of S-S-02, "Measurement Uncertainty and Meter Conformity Evaluation Specifications", following is a partial list of measurement uncertainty contributors that may influence conformity assessment a typical gas measuring apparatus. Their applicability will depend on the design of the measuring apparatus and the choice of the reference standard. The recommended method for their determination is presented with each of the contributors listed:

(a) Repeatability of device under test:

(i) Repeatability of device under test (Type A evaluation)

(b) Resolution uncertainties:

(i) Resolution of the pressure, temperature and barometer indications (process instruments) (Type B evaluation) (square distribution)

(ii) Pulse counting resolutions of the reference standard and device under test (Type B evaluation) (triangular distribution)

(c) Environmental performance uncertainties (influence quantities):

(i) Temperature and pressure sensitivity of reference standard calibration/performance (Type B evaluation) (square distribution – limited info)

(ii) Temperature and pressure sensitivity of the process Instrumentation (Type B evaluation) (square distribution – manufacturer's data)

(d) System design and operation uncertainties:

(i) Put in / Take out reproducibility of the device-under-test (Type A evaluation) (normal distribution – by experiment)

(ii) Long-term stability (LTS) of process instrumentation (Type A evaluation or Type B evaluation) (normal distribution – SPC charts

(iii) Sensitivity of reference standard's performance to operating rate (Type B evaluation)

(iv) Influence of the location of sensors relative to the desired measurement point (Type A evaluation or Type B evaluation)

(e) Uncertainties of the calibration the reference standards contained in the measuring apparatus (often referred to as fossilized uncertainty):

(i) Calibration of reference standard (Type A evaluation or Type B evaluation) (normal distribution)

(ii) Calibration of process instrumentation (Type A evaluation or Type B evaluation) (normal distribution)

(f) Operator performance:

(i) Reproducibility of operator's ability to read instrumentation - parallax errors (Type A evaluation or Type B evaluation) (square distribution or normal distribution)

(g) Uncertainties from assumptions:

(i) Compressibility and Z / Z assumptions (Type B evaluation) (square distribution)

(ii) Equation of state and algorithms (Type B evaluation) (square distribution)

(iii) Temperature and pressure effects – changes in the connecting volume (Type B evaluation) (square distribution)

(iv) The use of an alternate pressure, temperature or test medium on the performance of the device under test (Type A evaluation or Type B evaluation)

5.3 General Guidelines for the determination of the effects introduced between the device under test's test conditions and usage conditions (S-S-02-E, section 5.1.4 (d))

5.3.1 For gas measuring devices, the effect of the use of an alternate pressure, temperature or test medium on the performance of the device under test compared to normal operating conditions needs to be assessed.

5.3.2 For electricity meters, the effect of the use of a measuring apparatus as an alternate source on the performance of the meter compared to normal operating conditions needs to be assessed.

5.4 General Comments on Measurement Uncertainty and MADT

Measurement Uncertainty may be a consideration with MADT determination. Generally however, the uncertainty of the difference between the high-load and low-load tests will be much smaller than the overall measurement uncertainty. This is because there is tendency of any bias errors and long-term drift terms to cancel each other in such a comparison. This results in an uncertainty that approaches the square root of 2 times the test repeatability. Where it is established that the repeatablity of the process uncertainty is much smaller than the tolerance band, then the uncertainty can be regarded as insignificant.

6.0 Guidelines on Homogeneity and Lot Formation

6.1 The purpose of random sampling is to ensure that the sample can be representative of a homogeneous lot. Requirements associated with lot homogeneity can be found in the device specification.

6.2 If an ASP wishes to combine, in one lot, various models or vintages of meters, then it is the ASPs responsibility to submit a request to MC with documentation supporting the claim that the models are homogeneous. The device owner is responsible to keep records. Since the meters usually remain in the owner's inventory for many years, it is advisable that a record system be structured to ensure those documents can be retrieved in the future.

6.3 The various actions and switching rule decisions and that are outlined in S-S-03 and S-S-04 applies to original inspection only.

6.4 Lot Splitting (the sub-division of lots) and LQ Jumping are not permitted. Both points will be a key element for QA Managers and Auditors who will need to confirm that appropriate action has been taken and that qualification requirements have been met. Furthermore, lots being presented should not be subdivided arbitrarily in order to create a long run. (Reference: ISO TR 8550, 6.2). To prevent that possibility, a factor of 0.5 to 1.5 of the historical or typical lot size is employed to ensure lot sizes are always within a consistent range.

7.0 Guidelines on S-S-03

7.1 Guidelines for Historical Evidence as noted in S-S-03 include the following:

(a) An ASP currently sampling under LMB-EG-04 is qualified for sampling for the devices currently listed in their accreditation manuals. The initial implementation grandfathering can only be used once per homogeneity grouping.

(b) Historical evidence should be based on data for the facility and device under review. Sampling evidence from other organizations is not sufficient for qualification purposes. The intent is to confirm the integrity of both the device being sampled and the process being used by applicants.

7.2 With respect to Limited Quantity Options, users can use the sampling requirements indicated in S-S-03 for small volume or limited volume purchases. The alternative of 100% inspection is always an option.

7.3 When applying the acceptance-sampling plan to a Brand New Technology, or after a New Process Implementation, the following steps should be followed:

(a) Initially, requires 100% inspection of the quantity specified in S-S-03.

(b) Secondly, requires completion of the qualification requirements that are specified in S-S-03.

8.0 Guidelines for Process Related Corrective Action Resolution

8.1 Documentation is a key part of any corrective action resolution process. The documentation should include procedures that describe the processes for detection, feedback control and for the correction of conditions adverse to quality that have affected the device or the process. The procedures should include the following:

(a) Stopping rules and actions in the event that lots continue to fail.

(b) Events, which would cause discontinuation of sampling.

(c) Escalation procedure.

8.2 The Corrective Action Resolution should typically include the following types of activities:

(a) Conduct immediate disposition.

(b) Conduct root cause analysis.

(c) Implement and evaluate corrective actions.

(d) Confirm and approve resolution.

8.3 Effective corrective action would normally be implemented prior to presentation of the next lot. However, since some actions may involve other parties (such as the supplier), or involve capital expenditures, the complete implementation of corrective action may take more time. Such time delays should not be used to delay any necessary actions. It is important that the ASP ensures the quality of the process. Consequently, the ASP should provide procedures to achieve that goal. For the documents referenced in this Bulletin, the term ”implemented”, as applied to corrective action, means that corrective action has been identified and carried out but not necessarily validated.

8.4 Corrective action may include discontinuation of sampling inspection under S-S-04 annex A or B; and if so, that would necessitate re-qualification of the production process under S-S-03.

8.5 Conditions that should result in corrective action may include:

(a) Failures, malfunctions and deficiencies in production processes, equipment or software.

(b) Inadequate procedures and documentation.

(c) Inadequate control of work.

(d) Non-compliance with procedures.

(e) Scheduling problems.

(f) Process not statistically capable of producing product in accordance with the specifications.

9.0 Guidelines on Stopping and Escalation Procedures

9.1 Stopping rules based on a sequence of lots cannot address all possibilities; without limiting other possibilities, the ASP should have documented procedures to address occurrences such as process disruptions or repeated failures due to the same or similar causes. The investigation and resulting recommendations could result in discontinuation of sampling inspection under annexes A and B of S-S-04.

9.2 If a cumulative number of lots in a sequence are not accepted on original inspection, then stopping rules are required and inspection should be discontinued pending action to improve quality. (Reference: ISO 2859-10, 2.11.)

9.3 In the event users are operating at LQ = 8.0% and have non-acceptance of 3 out of 5 (or optionally 2 out of 3) consecutive original lots, then sampling can continue at 3.15%, unless evidence suggests that sampling is no longer appropriate (re-qualification would then be necessary).

9.4 In the event users are operating at LQ = 3.15%, and have non-acceptance of 3 out of 5 (or optionally 2 out of 3) consecutive original lots, then sampling will be suspended to perform corrective actions and re-qualification must be initiated. To re-qualify the process, S-S-03 would be utilized.

9.5 Information obtained from sampling several lots in sequence may indicate that process concerns are warranted. That should result in using the S-S-03 specification to invoke more rigorous sampling procedures. Sampling under S-S-03 provides consumer protection against poor quality; however, there is a higher risk to the producer of having an acceptable lot judged unacceptable. The indication of possible deterioration in product quality is a signal to initiate corrective action and it is important to ensure corrective action is taken. (Reference: ISO 2859-10, 2.5.1.)

9.6 100% Inspection is always an option to address quality control issues.100% inspection should be used until process related concerns have been addressed. (Reference: ISO TR 8550, 4.)

10.0 Guidelines on Sampling Plan Change Selection:

10.1 S-S-03 (Process Re-qualification) should be used after a significant change in production. Change in production infers new process or other substantial change. (Reference: ISO TR 8550, 6.2.)

10.2 With regard to the Isolated Lot Plan:

(a) There are no timeline restrictions.

(b) A significant change in process requires re-qualification as per S-S-03.

10.3 With regard the Short Series of Lots Plan:

(a) After a single stoppage over 6 weeks, then re-start at n1.

(b) For delivery time periods expected to be over 6 weeks, then revert to isolated lot option.

(c) A significant change in process requires re-qualification as per S-S-03.

11.0 Guidelines on Short Series or Isolated Lot Inspection

11.1 Typically, an ASP would use the isolated lot inspection process as defined in S-S-04 Annex A, unless they can meet the criteria for a short series. Typically, an accredited manufacturer would utilize S-S-04 Annex B when production quality stability has been demonstrated over a series of lots. Otherwise, the isolated lot plan should be used. (Reference: ISO 2859-10, 2.5.2.)

11.2 An isolated lot can be one in which a single lot has been purchased from a series of lots. (References: ISO 2859-10, 3.17 and ISO TR 8550, 5.2c.)

11.3 If the ASP decides not to implement S-S-04, Annex B (short series of lots), then S-S-04, Annex A (isolated lots) may be used. For an ASP processing limited quantities, the processes described in S-S-03 could be utilized for sampling inspection.

11.4 The general rules to utilize S-S-04, Annex B (short series of lots) are:

(a) Minimum of 5 lots will be presented in sequence.

(b) The maximum tolerable time period between successive lots is 6 weeks.

(c) If any of these conditions are not met, then revert to isolated lot option.

12.0 Guidelines on Inspection of Isolated Homogeneous Lots, S-S-04, Annex A

Under Annex A, there is the potential for a wide range of activities. Lots may be presented in isolation or the ASP may elect to inspect all lots under this annex. To provide consistency between Annex A and B of S-S-04, the following guidelines should be followed:

12.1 If an isolated lot is presented, then any action is limited to what is stated in section 4.4 of ISO 2859-2. If there are follow-on lots, then corrective action would be similar to that stated under Annex B. If an isolated lot were presented, then how to deal with a rejected lot would be limited to what is stated in section 4.4 of ISO 2859-2. If there are follow-on lots, then subsequent lots would be dealt with as per the requirements under Annex B (i.e. may be inspected under LQ 3.15 or 100% or undergo re-qualification of the process).

12.2 If process performance has degraded significantly, then sampling under Annex A or B should be discontinued, necessitating re-qualification as per S-S-03.

13.0 Guidelines on Rounding and Significant Figures

13.1 Discrimination is the degree of exactness with which the quantity is stated (i.e. the smallest readable unit, or the measurement resolution). The discrimination of a quantity refers to the right-most significant digit.

13.2 During calculations caution should be taken to ensure errors are not introduced due to the lack of figures. To avoid introducing error, rounding should only be done at the end of the calculation process. To achieve this the specification uses the term “one step”, referring to a procedure in which rounding is only performed once during calculations.

14.0 Process Flowcharts References

14.1 The flowcharts shown in Appendices A, B, and C of this bulletin are provided for reference purposes only. These flow charts depict a high-level overview of the basic process options only. Specifications S-S-03 and S-S-04 should be referenced for detailed information on the basic process and the numerous additional options that are available.

14.2 The flowcharts in the appendices reference the following documents:

(a) S-S-04 – Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots – Annex A

(b) S-S-04 – Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots – Annex B

(c) S-S-03 – Prerequisites to the Use of Sampling Inspection – Annex A

15.0 Additional Information

For additional information regarding this bulletin, please contact the Senior Program Officer responsible for electricity or gas measurement. For more information regarding Measurement Canada and its programs, visit our Web site located at http://mc.ic.gc.ca.

Gilles Vinet
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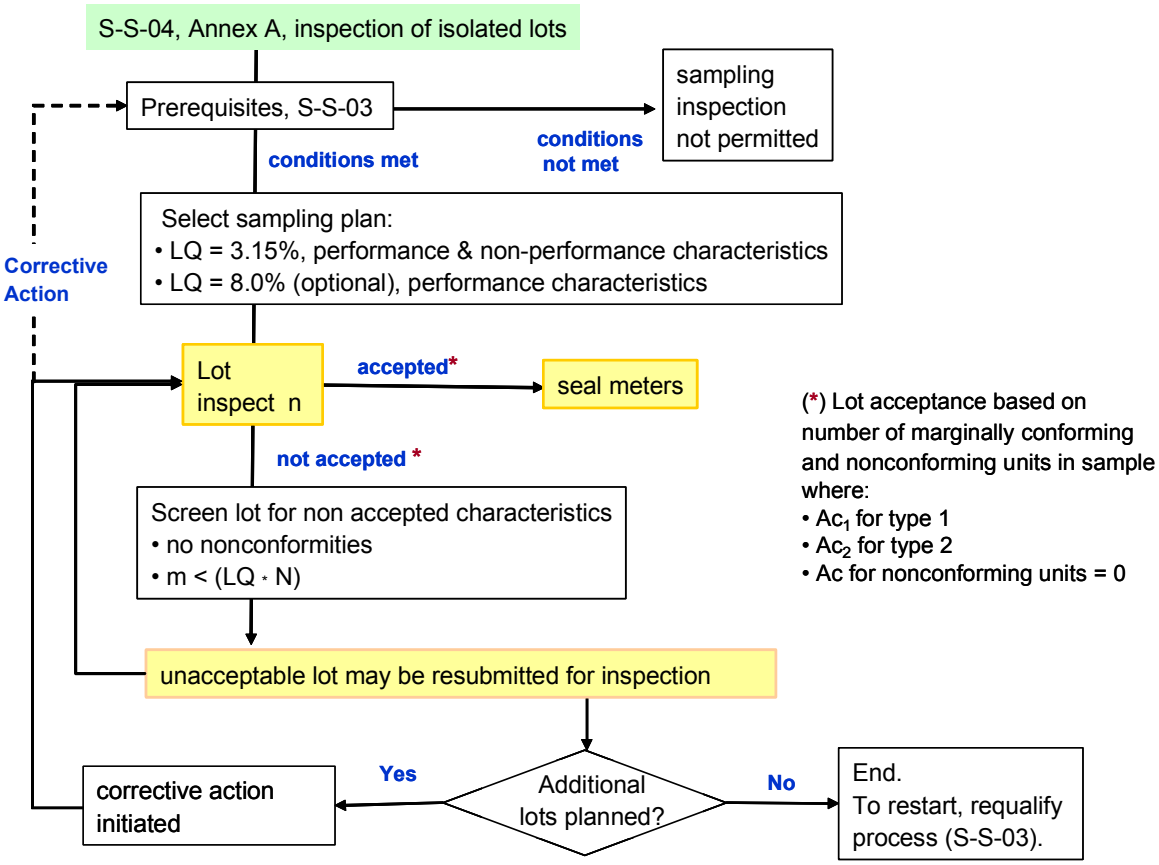
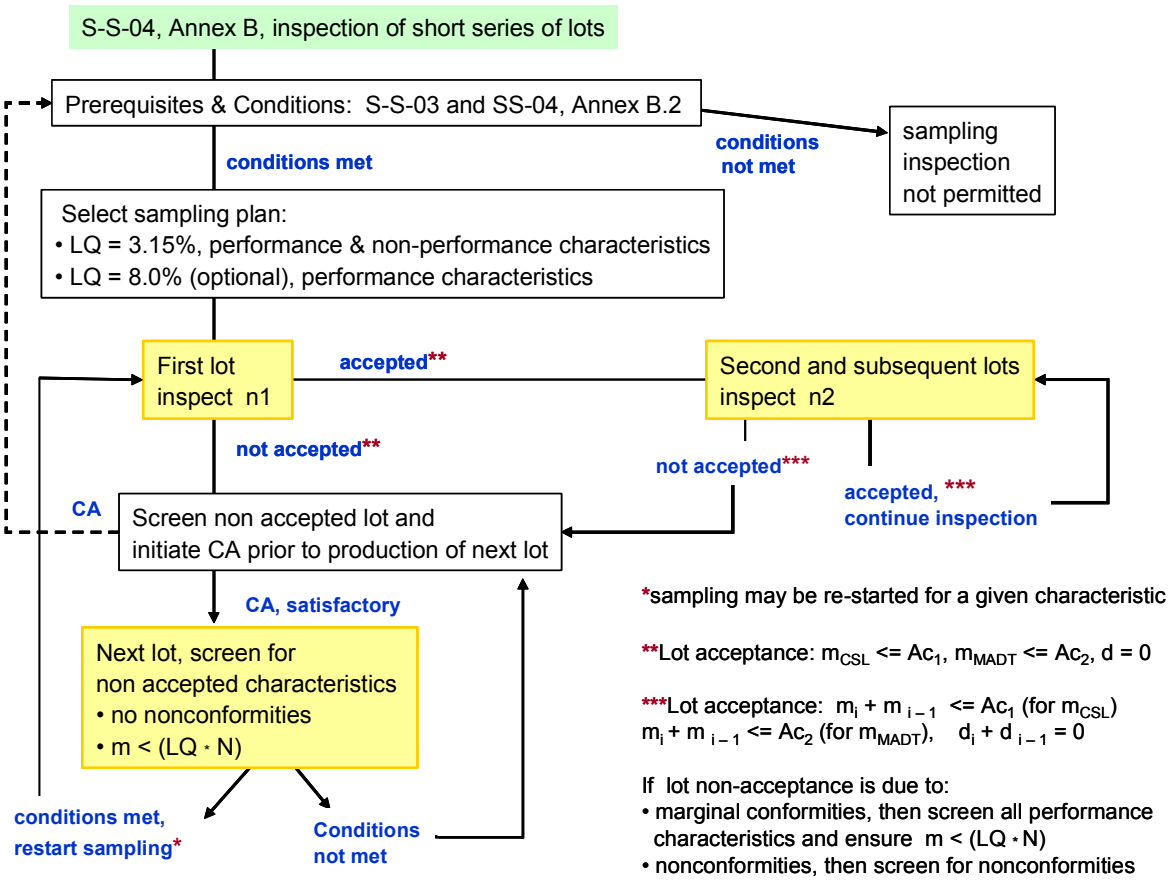
Appendix A

S-S-04 – Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots – Annex A



Appendix B

S-S-04 – Sampling Plans for the Inspection of Isolated Lots and Short Series of Lots – Annex B



Appendix C

S-S-03 – Prerequisites to the Use of Sampling Inspection, Annex A