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Standard Guide for Optimizing, Controlling and Reporting Test Method Uncertainties from Multiple Workstations in the Same Laboratory Organization[1]

This standard is issued under the fixed designation D6689; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes a protocol for optimizing, controlling, and reporting test method uncertainties from multiple workstations in the same laboratory organization. It does not apply when different test methods, dissimilar instruments, or different parts of the same laboratory organization function independently to validate or verify the accuracy of a specific analytical measurement.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1129 Terminology Relating to Water

D6091 Practice for 99 %/95 % Interlaboratory Detection Estimate (IDE) for Analytical Methods with Negligible Calibration Error

D6512 Practice for Interlaboratory Quantitation Estimate

E135

E415 Test Method for Analysis of Carbon and Low-Alloy Steel by Spark Atomic Emission Spectrometry

E1763 Guide for Interpretation and Use of Results from Interlaboratory Testing of Chemical Analysis Methods

STP 15D ASTM Manual on Presentation of Data and Control Chart Analysis, Prepared by Committee E11 on Statistical Methods

2.2 *Other Documents:*

ISO 17025 (previously ISO Guide 25) General Requirements for the Competence of Calibration and Testing Laboratories[3]

3. Terminology

3.1 *Definitions*—For definitions of terms used in this Guide, refer to Terminology E135 and D1129.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *laboratory organization*—a business entity that provides similar types of measurements from more than one workstation located in one or more laboratories, all of which operate under the same quality system.

NOTE 1—Key aspects of a quality system are covered in ISO 17025 and include documenting procedures, application of statistical control to measurement processes and participation in proficiency testing.

3.2.2 *maximum deviation*—the maximum error associated with a report value, at a specified confidence level, for a given concentration of a given element, determined by a specific method, throughout a laboratory organization.

3.2.3 *measurement quality objectives*—a model used by the laboratory organization to specify the maximum error associated with a report value, at a specified confidence level.

3.2.4 *workstation*—a combination of people and equipment that executes a specific test method using a single specified measuring device to quantify one or more parameters, with each report value having an established estimated uncertainty that complies with the measurement quality objectives of the laboratory organization.

4. Significance and Use

4.1 Many analytical laboratories comply with accepted quality system requirements such as NELAC chapter 5 (see Note 2) and ISO 17025. When using standard test methods, their test results on the same sample should agree with those from other similar laboratories within the reproducibility estimates (R2) published in the standard. Reproducibility

[1] This guide is under the jurisdiction of ASTM Committee D19 on Water and is the direct responsibility of Subcommittee D19.02 on Quality Systems, Specification, and Statistics.

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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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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estimates are generated during the standardization process as part of the interlaboratory studies (ILS). Many laboratories participate in proficiency tests to confirm that they perform consistently over time. In both ILS and proficiency testing protocols, it is generally assumed that only one workstation is used to generate the data (see 6.5.1).

NOTE 2—NELAC chapter 5 allows the use of a Work Cell where multiple instruments/operators are treated as one unit: the performance of the Work Cell is tracked rather than each workstation independently. This guide is intended to go beyond the Work Cell to achieve the benefits of monitoring workstations independently.

4.2 Many laboratories have workloads and/or logistical requirements that dictate the use of multiple workstations. Some have multiple stations in the same area (central laboratory format). Others' stations are scattered throughout a facility (at-line laboratory format). Often, analysis reports do not identify the workstation used for the testing, even if workstations differ in their testing uncertainties. Problems can arise if clients mistakenly attribute variation in report values to process rather then workstation variability. These problems can be minimized if the laboratory organization sets, complies with, and reports a unified set of measurement quality objectives throughout.

4.3 This guide can be used to harmonize calibration and control protocols for all workstations, thereby providing the same level of measurement traceability and control. It streamlines documentation and training requirements, thereby facilitating flexibility in personnel assignments. Finally, it offers an opportunity to claim traceability of proficiency test measurements to all included workstations, regardless on which workstation the proficiency test sample was tested. The potential benefits of utilizing this protocol increase with the number of workstations included in the laboratory organization.

4.4 This guide can be used to identify and quantify benefits derived from corrective actions relating to under-performing workstations. It also provides means to track improved performance after improvements have been made.

4.5 It is a prerequisite that all users of this guide comply with ISO 17025, especially including the use of documented procedures, the application of statistical control of measurement processes, and participation in proficiency testing.

4.6 The general principles of this protocol can be adapted to other types of measurements, such as mechanical testing and on-line process control measurements such as temperature and thickness gauging. In these areas, users will likely need to establish their own models for defining measurement quality objectives. Proficiency testing may not be available or applicable.

4.7 It is especially important that users of this guide take responsibility for ensuring the accuracy of the measurements made by the workstations to be operated under this protocol. In addition to the checks mentioned in 6.2.3, laboratories are encouraged to use other techniques, including, but not limited to, analyzing some materials by independent methods, either within the same laboratory or in collaboration with other equally competent laboratories. The risks associated with generating large volumes of data from carefully harmonized, but incorrectly calibrated multiple workstations are obvious and must be avoided.

5. Summary

5.1 Identify the Test Method and establish the required measurement quality objectives to be met throughout the laboratory organization.

5.2 Identify the workstations to be included in the protocol and harmonize their experimental procedures, calibrations and control strategies to be identical, so they will be statistically comparable.

5.3 Tabulate performance data for each workstation and ensure that each workstation complies with the laboratory organization's measurement quality objectives.

5.4 Document items covered in 5.1 – 5.3.

5.5 Establish and document a laboratory organization-wide Proficiency Test Policy that provides traceability to all workstations.

5.6 Operate each workstation independently as described in its associated documentation. If any changes are made to any workstation or its performance levels, document the changes and ensure compliance with the laboratory organization's measurement quality objectives.

6. Procedure

6.1 Identify the Test Method and establish the measurement quality objectives to be met throughout the laboratory organization.

6.1.1 Multi-element test methods can be handled concurrently, if all elements are measured using common technology, and the parameters that influence data quality are tabulated and evaluated for each element individually. An example is Test Method E415 that covers the analysis of plain carbon and low alloy steel by optical emission vacuum spectrometry. Workstations can be under manual or robotic control, as long as the estimated uncertainties are within the specified measurement quality objectives. Avoid handling multi-element test methods that concurrently use different measurement technologies. Their procedures and error evaluations are too diverse to be incorporated into one easy-to-manage package.

6.1.2 Set the measurement quality objectives for the use of the Test Method throughout the laboratory organization, using customer requirements and available performance data. At the conclusion of this effort, the laboratory organization will know the maximum deviation allowable for any report value, at any concentration level, using the method of choice. An example of a possible method for establishing measurement quality objectives is given in Appendix X1.

6.2 Identify the workstations to be included in the protocol and harmonize their experimental procedures, calibrations and control strategies so that all performance data from all workstations are directly statistically comparable.

6.2.1 For each workstation, list the parameters (personnel, equipment, etc.) that significantly influence data quality. Each

component of each workstation does not have to be identical (such as from the same manufacturer or model number). However, each workstation must perform the functions described in the test method.

6.2.2 Harmonize the experimental procedures associated with each workstation to ensure that all stations are capable of generating statistically comparable data that can be expected to fall within the maximum allowable limits for the laboratory organization. Ideally, all workstations within the laboratory organization will have essentially the same experimental procedures.

TABLE 1 Sample SPC Control Parameter Tabulation

E	RM	Assumed True Conc.	WS	Av.	UCL	LCL	Std. Dev.
C	638	0.06014	1	0.05996	0.06764	0.05228	0.00256
			2	0.06040	0.06364	0.05716	0.00108
			3	0.06005	0.06308	0.05702	0.00101
	648	0.25665	1	0.25212	0.27069	0.23355	0.00619
			2	0.25923	0.27402	0.24444	0.00493
			3	0.25861	0.27283	0.24439	0.00474
Mn	638	0.29832	1	0.29620	0.30304	0.28936	0.00228
			2	0.29967	0.30567	0.29367	0.00200
			3	0.29908	0.30643	0.29173	0.00245
	648	0.90328	1	0.90408	0.92088	0.88728	0.00564
			2	0.90408	0.92385	0.88431	0.00659
			3	0.90168	0.92664	0.87672	0.00832
P	638	0.00563	1	0.00543	0.00600	0.00486	0.00019
			2	0.00575	0.00605	0.00545	0.00010
			3	0.00571	0.00601	0.00541	0.00010
	648	0.03431	1	0.03413	0.03674	0.03152	0.00087
			2	0.03447	0.03702	0.03192	0.00085
			3	0.03434	0.03689	0.03179	0.00085
S	638	0.01820	1	0.01702	0.02146	0.01258	0.00148
			2	0.01868	0.02153	0.01583	0.00095
			3	0.01891	0.02128	0.01654	0.00079
	648	0.02424	1	0.02330	0.02771	0.01889	0.00147
			2	0.02475	0.02940	0.02010	0.00155
			3	0.02467	0.02884	0.02050	0.00139
Si	638	0.01688	1	0.01565	0.01718	0.01412	0.00051
			2	0.01755	0.01863	0.01647	0.00036
			3	0.01743	0.01830	0.01656	0.00029
	648	0.23283	1	0.22900	0.23911	0.21889	0.00337
			2	0.23240	0.24404	0.22076	0.00388
			3	0.23710	0.24619	0.22801	0.00303
Cu	638	0.26588	1	0.26685	0.27555	0.25815	0.00290
			2	0.26569	0.27295	0.25843	0.00242
			3	0.26511	0.27276	0.25746	0.00255
	648	0.10700	1	0.10654	0.11089	0.10219	0.00145
			2	0.10753	0.11086	0.10420	0.00111
			3	0.10694	0.13784	0.07604	0.01030
Ni	638	0.69005	1	0.70014	0.72516	0.67512	0.00834
			2	0.68252	0.69440	0.67064	0.00396
			3	0.68750	0.71309	0.66191	0.00853
	648	0.25063	1	0.25174	0.25906	0.24442	0.00244
			2	0.24891	0.25350	0.24432	0.00153
			3	0.25123	0.25927	0.24319	0.00268
Cr	638	0.03746	1	0.03760	0.03886	0.03634	0.00042
			2	0.03745	0.03832	0.03658	0.00029
			3	0.03732	0.03813	0.03651	0.00027
	648	0.23728	1	0.23190	0.23637	0.22743	0.00149
			2	0.24012	0.24414	0.23610	0.00134
			3	0.23982	0.24300	0.23664	0.00106
Sn	638	0.00278	1	0.00255	0.00507	0.00003	0.00084
			2	0.00257	0.00296	0.00218	0.00013
			3	0.00322	0.00490	0.00154	0.00056
	648	0.01424	1	0.01402	0.01600	0.01204	0.00066
			2	0.01412	0.01502	0.01322	0.00030
			3	0.01458	0.01668	0.01248	0.00070
Mo	638	0.06346	1	0.06253	0.06604	0.05902	0.00117
			2	0.06398	0.06533	0.06263	0.00045
			3	0.06387	0.06621	0.06153	0.00078
	648	0.08652	1	0.08539	0.08995	0.08083	0.00152
			2	0.08722	0.08941	0.08503	0.00073
			3	0.08696	0.09011	0.08381	0.00105
V	638	0.02107	1	0.02076	0.02184	0.01968	0.00036
			2	0.02114	0.02219	0.02009	0.00035
			3	0.02132	0.02231	0.02033	0.00033
	648	0.06937	1	0.06892	0.07123	0.06661	0.00077
			2	0.06949	0.07219	0.06679	0.00090
			3	0.06969	0.07233	0.06705	0.00088
Ti	638	0.00224	1	0.00272	0.00296	0.00248	0.00008
			2	0.00200	0.00200	0.00200	0.00000
			3	0.00200	0.00200	0.00200	0.00000
	648	0.04279	1	0.04285	0.04726	0.03844	0.00147
			2	0.04285	0.04684	0.03886	0.00133
			3	0.04268	0.04688	0.03848	0.00140
Al	638	0.02346	1	0.02373	0.02964	0.01782	0.00197
			2	0.02343	0.02646	0.02040	0.00101
			3	0.02323	0.02584	0.02062	0.00087
	648	0.06268	1	0.06268	0.06721	0.05815	0.00151
			2	0.06198	0.06633	0.05763	0.00145
			3	0.06222	0.06576	0.05868	0.00118

E = Element determined
RM = Reference material used for SPC control
Assumed True Conc. = Concentration of E in the RM
WS = Work Station
Av. = Grand Mean from the SPC chart
UCL = Upper control limit from the SPC chart
LCL = Lower control limit from the SPC chart
Std. Dev. = Standard Deviation from the SPC chart {(UCL-LCL)/6}

6.2.3 Harmonize calibration protocols so that equivalent calibrants (i.e. same material source, same stock solutions) are used to cover the same calibration ranges for the same elements on all instruments (see Note 3). Avoid the use of different calibrants on different instruments that may lead to calibration biases and uncertainties that are larger than necessary. Make sure that all interferences and matrix effects are accounted for. Verify the calibrations with certified reference materials not used in the calibration, when possible. Record the findings for each workstation.

NOTE 3—It is recommended that the same calibrants are used for each instrument, i.e. same material source, same stock solution, etc. when practical. Calibrations on all Workstations must be performed within a time period such that the stability of the calibration standards are not a concern, if applicable.

6.2.4 Use the same Statistical Process Control (SPC) materials and data collection practices on all workstations (see Note 4). Carry SPC materials through all procedural steps that contribute to the measurement uncertainty. Develop control charts in accordance with , or equivalent. Do not develop control charts using SPC data from more than one instrument because this does not allow for adequate trend analysis of the instrument performance.

NOTE 4—Generally, it is recommended that SPC concentrations be set about ⅓ from the top and ⅓ from the bottom of each calibration range. It is also recommended that single point, moving range charts be used so that calculated standard deviations reflect the normal variation in report values.

6.2.5 Collect at least 20 SPC data points from each workstation to ensure that the workstations are under control and that the control limits are representative.

6.3 Tabulate performance data for each workstation and ensure that each workstation complies with the laboratory organization's measurement quality objectives.

6.3.1 Tabulate the SPC data by parameter (element), Reference material, assumed true concentration, workstation, average, upper control limit, lower control limit, and standard deviation, as illustrated in Table 1.

NOTE 5—The data in Table 1 were collected over an extended time period on two reference materials using three optical emission spectrometers in a large, integrated steel mill. The data is typical of that produced in ISO 17025 compliant laboratory prior to the availability of this guide.

NOTE 6—The assumed true concentration is the average of the average concentrations from each control chart. When all workstations are calibrated in accordance with 6.2.3 and all SPC charts are generated in accordance with 6.2.4, the grand means for each element/material combination should be sufficiently similar so as not to contribute significantly to the overall uncertainty of the method.

6.3.2 Using the maximum allowable uncertainty for the laboratory organization as described in 6.1.2, establish the maximum upper control limits and the minimum lower control limits to be allowed for each element/concentration in the SPC program.

6.3.2.1 As shown in the example in Table 2, list the element, the SPC reference material, and the assumed true concentration for the reference material.

6.3.2.2 Using the laboratory organization-wide model for defining maximum deviations, pick and record the Maximum Deviation to be allowed, noting the confidence level at which the maximum deviation was defined.

6.3.2.3 From the values determined in 6.3.2.2, calculate the maximum upper control limit and minimum lower control limit the laboratory organization will allow on any workstation in the program. Refer to Table 2 for a completed example using the model described in Appendix X1.

NOTE 7—In the example given, the numbers in the Maximum Deviation column in Table 2 were taken from the Model in Appendix X1. The maximum deviation value (95 % confidence), associated with each concentration value was divided by 2 and then multiplied by 3, and then either added to (upper control limit) or subtracted from (lower control limit) the assumed true concentration.

6.3.3 Compare the upper and lower control limits observed in the laboratory (see examples in Table 1) with the maximum allowed values (see examples in Table 2). Any observed value that control limit that exceeds an associated maximum allowed limit is to be considered out of compliance with the laboratory's measurement quality objectives and should be investigated and corrected as appropriate.

NOTE 8—A review of the data in Table 1 indicates that the control data on some elements violates the measurement quality objectives defined in Appendix X1. This is to be expected when applying a model to a data set after the data set was developed instead of prior to the application of the measurement quality objective criteria throughout the laboratory organization, as the standard requires.

6.3.3.1 High standard deviations for any item across all workstations may indicate a problem with the homogeneity of the SPC material.

NOTE 9—The standard deviations for carbon in RM 648 exceeded the expected precision on all three workstations by a small amount, suggesting a possible material problem. Homogeneity of a reference is generally not a consideration for aqueous calibration standards.

6.3.3.2 High standard deviations for any element on any workstation, especially if it shows on more than one SPC material, may indicate a precision problem with that channel on that instrument.

NOTE 10—Except for the issue described in Note 8, Workstation 1 showed a high standard deviation for C, S, Sn, and Al for RM 638. Since the precision on all other workstations was acceptable for these elements, the data suggest that Workstation 1 should be investigated for possible corrective action.

6.3.3.3 Establish an internal audit procedure to ensure that all workstations continuously perform within the expected boundaries.

TABLE 2 Sample of Maximum Deviations with Corresponding

E	RM	Conc.	Maximum Deviation	Sigma (max. dev./2)	Sigma *3	Maximum UCL	Minimum LCL
C	638	0.06014	0.003226	0.00161288	0.0048386	0.064979	0.055301
C	648	0.25665	0.008421	0.00421054	0.0126316	0.269282	0.244018
Mn	638	0.29832	0.009302	0.00465102	0.0139530	0.312273	0.284367
Mn	648	0.90328	0.019353	0.00967666	0.0290300	0.932310	0.874250
P	638	0.00563	0.000674	0.00033678	0.0010104	0.006640	0.004620
P	648	0.03431	0.002226	0.00111279	0.0033384	0.037648	0.030972
S	638	0.01820	0.001463	0.00073169	0.0021951	0.020395	0.016005
S	648	0.02424	0.001769	0.00088437	0.0026531	0.026893	0.021587
Si	638	0.01688	0.001392	0.00069615	0.0020884	0.018968	0.014792
Si	648	0.23283	0.007896	0.00394787	0.0118436	0.244674	0.220986
Cu	638	0.26588	0.008620	0.00431008	0.0129302	0.278810	0.252950
Cu	648	0.10700	0.004722	0.00236087	0.0070826	0.114083	0.099917
Ni	638	0.69005	0.016197	0.00809827	0.0242948	0.714345	0.665755
Ni	648	0.25063	0.008290	0.00414497	0.0124349	0.263065	0.238195
Cr	638	0.03746	0.002359	0.00117934	0.0035380	0.040998	0.033922
Cr	648	0.23728	0.007995	0.00399761	0.0119928	0.249273	0.225287
Sn	638	0.00278	0.000422	0.0002112	0.0006336	0.003414	0.002146
Sn	648	0.01424	0.001244	0.00062209	0.0018663	0.016106	0.012374
Mo	638	0.06346	0.003342	0.00167122	0.0050137	0.068474	0.058446
Mo	648	0.08652	0.004103	0.00205142	0.0061543	0.092674	0.080366
V	638	0.02107	0.001612	0.00080608	0.0024182	0.023488	0.018652
V	648	0.06937	0.003545	0.00177259	0.0053178	0.074688	0.064052
Ti	638	0.00224	0.000366	0.00018309	0.0005493	0.002789	0.001691
Ti	648	0.04279	0.002576	0.0012878	0.0038634	0.046653	0.038927
Al	638	0.02346	0.001731	0.00086544	0.0025963	0.026056	0.020864
Al	648	0.06268	0.003315	0.00165761	0.0049728	0.067653	0.057707

6.4 Document items covered in 6.1 – 6.3.

6.5 Implement and document a laboratory organization-wide Proficiency Test Policy that provides traceability to all workstations.

6.5.1 Establish a laboratory organization-wide policy for assigning incoming Proficiency Test samples to the workstations and demonstrating traceability (applicability) of results to all workstations based on the elements contained in this guide. That policy might call for proficiency test samples to be analyzed on a rotating basis among all workstations or selecting workstations on a random basis. It must also include provision for confirming the acceptability of proficiency test results and confirmation that all workstations were in statistical control at the time the proficiency test samples were analyzed.

6.6 Operate each workstation independently as defined in its associated documentation. If any changes are made to any workstation or its performance levels, document the changes and ensure compliance with the laboratory organization's measurement quality objectives.

7. Keywords

7.1 accreditation; proficiency testing; workstation

APPENDIX

(Nonmandatory Information)

X1. A SUGGESTED MODEL FOR ESTABLISHING LABORATORY MEASUREMENT QUALITY OBJECTIVES

X1.1 Scope

X1.1.1 The establishment of clearly defined measurement quality objectives is an essential first step in establishing procedures to harmonize the control of measurement uncertainties resulting from the use of multiple workstations. Measurement quality objectives must be stringent enough to meet all major client demands, including process control, specification conformity testing, and proficiency testing requirements. On the other hand, if they are set too stringently, the laboratory staff will find it difficult to meet them, and the laboratory will suffer significant productivity losses. This Appendix presents one model that an analytical chemistry laboratory can use to establish the measurement quality objectives needed to comply with this guide.

NOTE X1.1—Although this model has many wider applications in testing laboratories, the discussion in this Appendix is limited to meeting the specific requirements of this guide.

X1.1.2 This model is based on the long-recognized fact that, assuming measurement processes are optimized and under control, the uncertainty increases with concentration in a manner that can be described by a straight line on a plot of log of uncertainty vs. log of concentration.[4] This fact paves the way for laboratories to use data from their specific work environments and with which they feel comfortable, to develop measurement quality objectives.

X1.1.3 The data used in this Appendix to represent the original R2 values is from a large number of interlaboratory tests of analytical methods carried out by ISO Technical Committee 17, Subcommittee 1 on Iron and Steel. These compilations represent typical performance levels of competent laboratories. The model permits individual laboratories to use these functions directly or to make adjustments to suit their individual needs.

X1.1.4 The model referenced in this section is a special case of the general model of analytical error proposed by Rocke and Lorenzato[5] and incorporated into both D6091 and D6512. This same model labeled "General Analytical Error Model" is the basis of E1763. The more general model where $S^2 = A^2 + (B+T)^2$ (where S = interlaboratory standard deviation, T = true analyte concentration, and A & B are constants) can be used with note that it defaults to S=B*T where there is no discernable error unrelated to true concentration. Of the large number datasets examined using the Rocke and Lorenzato model, very few fit the above default when concentrations from the blank up to the IQE_{20} % are included in the studies.

X1.2 Assumptions

X1.2.1 For any determination, the reproducibility (difference in report values between two competent laboratories analyzing the same sample, at 95 % confidence) will be less than the R2 value shown on Fig. X1.1.

X1.2.2 For any determination, the repeatability (difference in report values between duplicates of the same sample made on the same workstation, at 95 % confidence) will be less than the R1 value shown on Fig. X1.1. The value of R1 is estimated by dividing R2 by the square root of two. The within-laboratory standard deviation (95 % confidence) is estimated by dividing R1 by the square root of two.

X1.2.3 Most measurements by competent laboratories using standard test methods have negligibly small components of bias. Therefore, this model for developing measurement quality objectives for measurement laboratories does not address bias.

X1.3 Procedure

X1.3.1 Establish the tolerable analytical uncertainty that the laboratory can achieve and meet its clients' needs.

X1.3.1.1 Prepare a log-log plot of R2 (95 % confidence) vs. concentration (%, m/m) using the ISO data, (described in X1.1.3) as shown in Fig. X1.1.

[4] Horwitz, W., Kamps, L.R. and Boyer, I. W. (1980) J. Assoc. Off. Anal. Chem. 63, 1344-1354.

[5] Rocke, D. M., Lorenzato, S. (1995) Technometrics, Vol. 37, No. 2, pp 176-184.

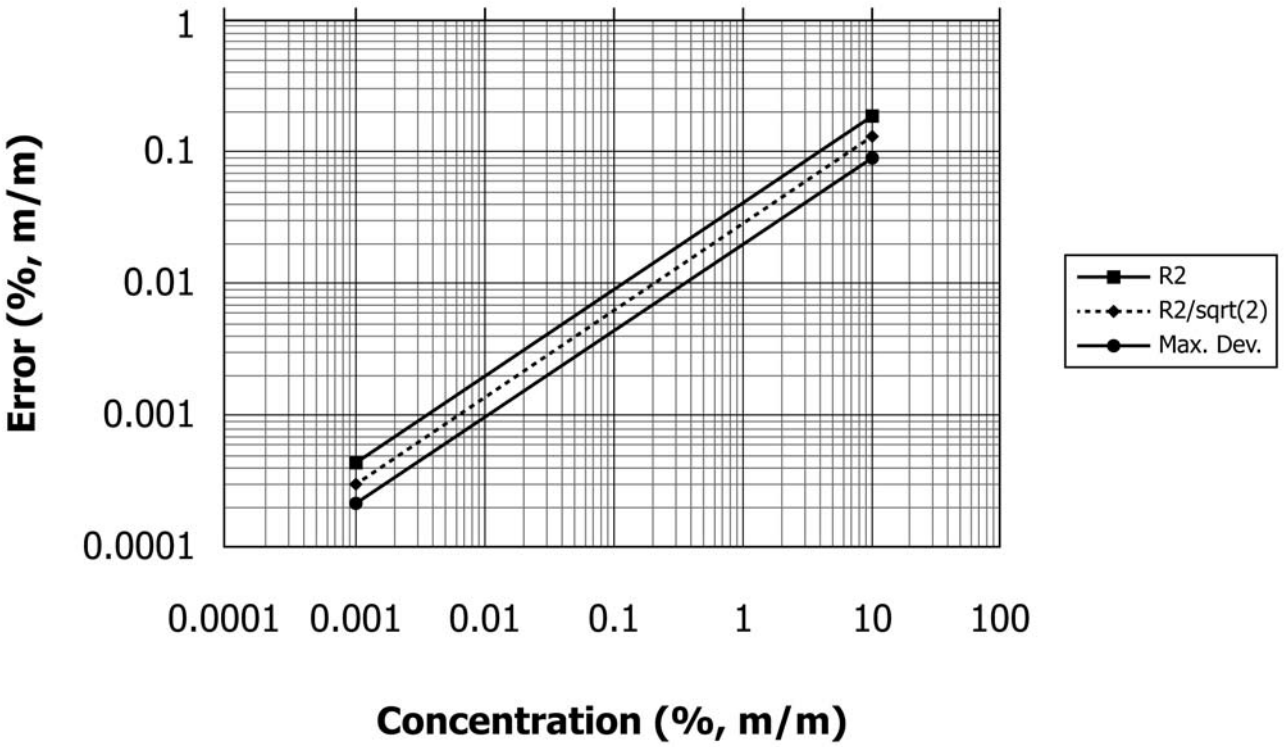

FIG. X1.1 Data Quality Objectives

X1.3.1.2 Add a second line to the plot where the individual R2 values are divided by the square root of two. It represents the maximum errors that the laboratory can have and still meet the R2 specification. Verify that all client obligations can be fulfilled if the laboratory reports results within the confines of the lower line. If the line does not meet customers' needs, make minor adjustments as necessary (see Note X1.2). This function becomes the official estimated uncertainty of the laboratory for all test results included in the evaluation.

NOTE X1.2—Experience shows that laboratories that significantly relax the requirements associated with the line are at greater risk of failing proficiency tests and of generally being less competent. On the other hand, laboratories that significantly tighten the requirements are likely to experience productivity losses and higher operating costs as staff attempts to meet performance goals that are generally unattainable with currently available methods and equipment.

X1.3.2 Establish the widest control limits to be permitted on SPC charts while remaining consistent with the target estimated uncertainties for the laboratory.

X1.3.2.1 Add a third line to the plot by dividing the among-laboratory standard deviations by the square root of 2. This remaining line estimates the maximum deviation (95 % confidence) to be allowed on SPC charts when homogeneous samples are carried through the process, except for variations related to the sample itself. Divide those values by 2 to obtain an estimate of one standard deviation, and multiply by three to obtain the three standard deviations to be used to establish upper and lower control limits for the SPC charts.

X1.3.2.2 This model sets the maximum upper and lower control limits for all SPC charts associated with all workstations included in the program. If any workstation is more precise than the target limits, then that workstation has a "safety factor" built in so that it can drift slightly out of control and still not cause the laboratory to report results that have uncertainties greater than those stated.

X1.3.2.3 This model does not specify a tolerance for bias among instruments. It is assumed that any bias in test results will be eliminated below statistical significance during the initial calibration procedure and maintained below statistically acceptable limits by the normal SPC practice of the laboratory.

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