# Managing Calibration Intervals<sup>1</sup>

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### Abstract

This paper presents guidelines for implementing calibration interval management systems as components of computerized general calibration management systems. In addition to optimizing calibration interval management, following these guidelines can significantly contribute to improving compliance with MIL-STD 45662A and ISO-9000.

### 1. Introduction

Calibration managers are faced with increasing pressures to minimize costs while improving compliance with "Rev. A" of MIL-STD-45662A, establishing compliance with ISO-9000, and improving the reliability of measurement and test equipment. By optimizing calibration intervals, unnecessary calibrations can be minimized, thereby reducing costs. Moreover, optimizing intervals will improve compliance with regulatory directives while ensuring maximal compliance with reliability targets.

This paper presents guidelines for implementing calibration interval management systems, as components of computerized calibration management systems, which can significantly contribute to the achievement of these objectives. These guidelines include both background material for offering practical insights for implementing many of the concepts of NCSL RP-1 [1] and database structures and elements needed for optimizing calibration interval management.

"Optimal" calibration intervals are considered those which can be established to meet in-tolerance percentage or *measurement reliability* quality objectives. Of the many approaches to calibration interval analysis currently in use, only statistical methodologies, such as method S2 of NCSL RP-1 have been found to meet this optimality criterion.<sup>2</sup> It is assumed throughout this paper that a statistical analysis methodology, such as NCSL RP-1 S2, is employed in the analysis of data.

It should be mentioned that method S2 of NCSL RP-1 focuses on interval analysis and adjustment at the manufacturer/model and instrument class (homogeneous grouping of manufacturer/models) levels. In

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<sup>&</sup>lt;sup>2</sup>Non-statistical or "algorithmic" [1] methods are suboptimal for several reasons. First, algorithmic methods usually involve shortening or lengthening intervals in response to the results (in- or out-of-tolerance) of current and one or two prior calibrations. Such schemes routinely shift items from correct intervals to incorrect ones as well as otherwise. Second, algorithmic methods are not suitable for adjusting intervals to meet desired reliability targets. Instead, achieved reliabilities iterate toward levels which are accidental byproducts of whatever adjustment algorithm is used. Finally, even under ideal circumstances, reaching these reliability levels requires between fifteen and sixty years. [2].

addition to these levels, this paper also considers calibration interval analysis and management by instrument parameter. Although many organizations analyze and adjust calibration intervals by instrument serial number, this practice is not encouraged unless analysis follows a statistical methodology and is based on sufficient data (see Footnotes 2 and 5).

With regard to parametric interval management, analysis at this level is becoming more feasible with increasing reliance on automated calibration. With automated calibration, readings are automatically taken by parameter. Automatic data storage and analysis are simple extensions of this process. Interval adjustment by parameter features several advantages over cruder alternatives. One such advantage is the potential for "stratified calibration" in which not all parameters are calibrated at each calibration.<sup>3</sup> As will be discussed later, converting from a set of parameter calibration intervals to an instrument recall cycle is fairly straightforward.

# 2. Background

Calibration intervals are established to ensure that test and measuring equipment (TME) are functioning within expected tolerance limits at time of use. Implicit in the application of calibration intervals is an assertion that TME parameter values may change over time and require periodic recalibration to be maintained within acceptable limits (tolerance limits). The fundamental concept behind this assertion is referred to as uncertainty growth.

### 2.1 Uncertainty Growth

Immediately following the calibration of a TME parameter, knowledge of the parameter's value can be quantified. This knowledge is embodied in an uncertainty statement. Such a statement accounts for measurement uncertainties arising from the calibration system, the calibration process, the calibrating environment, the calibrating technician or automated device, and the parameter under calibration.

As time passes from the date of calibration, knowledge of the parameter's value becomes increasingly vague. This is due to potential responses of the parameter to stresses encountered during shipping, handling, usage and storage. Indeed, certain highly precise and sensitive parameters may shift values as a result of random thermal motion of constituent molecules or even as a result of quantum mechanical processes.

Because of potential parameter value changes, an uncertainty component which grows with time since calibration must be added to the uncertainties accompanying the calibration process. Figure 1 exemplifies this uncertainty component for a parameter whose value is known to drift linearly with time. Note that in the example shown, although an equation can be applied which projects parameter change or "error" growth over time, a degree of uncertainty still exists as to the accuracy of this projection.<sup>4</sup>

 $<sup>^{3}</sup>$ We wouldn't consider paying for a full 90,000 mile service at every routine checkup of the family car. Should we be less frugal with TME calibrations?

<sup>&</sup>lt;sup>4</sup> This example distinguishes between "error," which manifests itself as a concrete parameter value deviation, and "uncertainty," which manifests itself as a lack of knowledge of the parameter value.



Time Since Calibration

**Figure 1. Uncertainty Growth Example.** The component of uncertainty due to uncertainty growth for a parameter which drifts linearly with time. As time elapses since calibration, less confidence can be placed in projected parameter values.

A statistical picture of the linear drift example of Figure 1 is provided in Figure 2 for a parameter characterized by symmetrical two-sided tolerance limits. In Figure 2, statistical distributions are portrayed for the parameter at times  $t_1 < t_2 < t_3$ . For each distribution, the shaded area represents the probability that the parameter is functioning in an out-of-tolerance state at the time in question. As time passes, the "spread" of the distributions increases. Consequently, the probability that the parameter is functioning in a out-of-tolerance state and the parameter is functioning in a out-of-tolerance state increases with time since calibration.

#### 2.2 Measurement Reliability

The probability that a TME parameter is functioning in an in-tolerance state is referred to as the parameter's measurement reliability. From the previous section, it can be concluded that TME parameter measurement reliability decreases with time since calibration. This is an unavoidable consequence of measurement uncertainty growth.

As Figure 2 shows, the magnitude of the measurement uncertainty of a TME parameter at time *t* is embodied in its statistical probability density function f(x(t)). Representing measurement reliability at time *t* by R(t) and TME parameter tolerance limits by  $L_1$  and  $L_2$ , the relationship between measurement reliability and f(x(t)) is given by the integral

$$R(t) = \int_{L_1}^{L_2} f(x(t)) dx \,. \tag{1}$$

Because of the direct link between measurement reliability and measurement uncertainty growth, uncertainty growth can be controlled by controlling measurement reliability. As will be seen, measurement reliability can be observed,



**Figure 2. Statistical Uncertainty Growth Description.** Probability density functions at three different times elapsed since calibration for the example in Figure 2. Shaded areas represent out-of-tolerance probabilities. As the uncertainty in the parameter value grows, the out-of-tolerance probability increases.

measured and predicted. Since calibration intervals are employed to control measurement uncertainty growth, measurement reliability turns out to be a useful statistic for establishing and adjusting calibration intervals.

#### 2.3 The Measurement Reliability Time Series

As stated earlier, measurement reliability is the probability that a TME parameter is functioning in an intolerance state. At any given time t elapsed since calibration, this probability can be sampled by performing some number of calibrations n(t). If the number of calibrations for which the parameter was found in-tolerance is represented by the variable g(t), then the sampled measurement reliability for time t is

$$\widetilde{R}(t) = \frac{g(t)}{n(t)}.$$
(2)

Sampling at different time intervals and arranging the samples in ascending or descending time interval order results in an observed measurement reliability time series. An example of such a time series is shown in Figure 3.



Figure 3. Example Measurement Reliability Time Series. Measurement reliability is sampled at various intervals between calibration (resubmission times). Samples are arranged in ascending resubmission time order.

This sampling procedure comprises a controlled experiment. To reiterate, the experiment involves three steps:

- 1. Samples of a given TME parameter are placed in use for different time intervals.
- 2. Each sample is evaluated to obtain an observed measurement reliability estimate using Eq. (2).
- 3. The estimates are arranged in ascending or descending order of calibration interval to obtain a measurement reliability time series.

Performing a controlled experiment to determine a measurement reliability time series is not ordinarily considered cost effective. Fortunately, such experiments are not necessary since their essential elements can be found in most TME calibration recall programs: Step 1 above is equivalent to returning equipment to service following calibration. Step 2 merely involves periodically calibrating TME and

sorting recorded calibrations into sampling intervals (e.g. two-week windows<sup>5</sup>) centered around nominal resubmission times (e.g., five weeks, ten weeks, fifteen weeks, etc.). Step 3 is trivial.

The important thing to bear in mind is that, if an in-place, operational calibration recall program is to be utilized as if it were a controlled experiment, then certain care must be taken to ensure that data are accurate, homogeneous and comprehensive for the experiment to be valid. These considerations will be discussed presently.

### 2.4 Measurement Reliability Modeling

Looking at Figure 3, it is tempting to fit some kind of curve to the observed data. Figure 4 shows the result of fitting a simple negative exponential model, characterized by the coefficients  $\lambda$  and  $R_0$ . Other models are possible. Selecting and fitting mathematical models to observed measurement reliability time series data is called measurement reliability modeling. In measurement reliability modeling, mathematical procedures are used to both select the most appropriate model and to achieve the best fit to the data. Fitting a given model to time series data consists of determining "best fit" values for the model's coefficients. The process is described in detail in NCSL RP-1 and elsewhere [1,3,4].



**Figure 4. Measurement Reliability Modeling.** Mathematical measurement reliability models are tested and fit to sampled time series data. The negative exponential model is shown. Many other reliability models are possible [1].

### 2.5 Calibration Interval Estimation

Once a reliability model has been selected and its coefficients evaluated, the model can be used to compute a calibration interval which corresponds to a desired level of measurement reliability. This desired level is referred to as the measurement reliability target. For example, denoting the measurement

<sup>&</sup>lt;sup>5</sup> Sampling windows should be large enough to contain five or more calibrations each, but small enough to provide a sufficient number of sampled measurement reliability points for time series modeling. The latter is ensured if the number of sampled measurement reliability points is greater than the number of coefficients of the measurement reliability model (see Section 2.4). Note that, if enough data can be accumulated that satisfies these criteria for an individual TME serial number, then calibration interval analysis and adjustment is feasible for the serial number. Ordinarily, however, extensive calendar time is required to amass sufficient data at the serial number level, and older data often need to be discarded as nonrepresentative. This makes the accumulation of sufficient serial number data next to impossible except in rare instances.

reliability target by  $R^*$ , if the exponential model shown in Figure 4 is applicable, then the calibration interval is computed according to

$$Interval = -\frac{1}{\lambda} \ln\left(\frac{R^*}{R_0}\right)$$
(3)

So, the process comes full circle. Calibration history data are taken and arranged in a time series. Measurement reliability modeling is employed to select an appropriate model for the time series and to determine the model's coefficients. The selected model, together with its coefficients, is then used to compute a calibration interval corresponding to an acceptable level of measurement reliability. Equipment are assigned this interval and calibrated periodically, thereby providing additional data for modeling the time series. The question remains, what data are to be taken? It turns out that the answer to this question depends on the specific TME level at which calibration interval analysis is to be performed.

# 3. Calibration Interval Analysis Levels

Although TME recall is managed at the serial number level, calibration interval analysis can be focused at several alternative levels. The choices available depend on the data recorded at time of calibration. The levels of analysis rigorously supported by current calibration interval analysis technology are

- Analysis by TME parameter parameter variables data
- Analysis by TME parameter parameter attributes data
- Analysis by TME model number instrument attributes data
- Analysis by TME class instrument attributes data.<sup>6</sup>

Although serial number analysis schemes based on instrument attributes data are in widespread use, a rigorous technology does not yet exist for analysis at this level. ("Rigorous" methods are considered those which follow the "experimental" procedure described in Section 2.) This is because not enough instrument attributes data can ordinarily be accumulated on an individual serial number to permit analysis using existing methods [2]. Research is underway however to develop methods for projecting individual TME parameter values as a function of time since calibration. When these methods come to fruition, calibration interval analysis at the serial number level may become possible.<sup>7</sup>

### 3.1 TME Parameter - Parameter Variables Data

Maximum flexibility and utility is attainable if the measurement reliability time series (Section 2) is based on variables data taken by TME parameter. Analysis at this level involves applying specified tolerance limits against variables data taken on each parameter, evaluating whether the parameter is in- or out-of-tolerance relative to these limits, and pooling parametric data by TME model number. The measurement reliability time series is constructed, measurement reliability modeling is applied to the time series, parameter measurement reliability targets are applied, and parameter intervals are computed

<sup>&</sup>lt;sup>6</sup> TME "Class" encompasses groupings of TME model numbers which are homogeneous with respect to application, accuracy, stability, complexity and technology [1].

<sup>&</sup>lt;sup>7</sup> Although mathematical methods are available for modeling parameter value changes over time, models covering the spectrum of TME parameter change mechanisms have not yet been formulated. Some progress has been made in areas where parameter values change linearly in response to mechanical stresses.

as described in Section 2. TME instrument recall intervals are determined from parameter intervals through measurement reliability networking or equivalent [5].<sup>8</sup>

Note that, since the in- or out-of-tolerance criteria used (i.e., the parameter tolerance limits) are not fixed externally, but rather are specified during analysis, the measurement reliability time series can be based on user defined parameter accuracy requirements. In addition, since parameter intervals are computed using parametric measurement reliability targets, TME calibration recall cycles can be managed in accordance with individual user needs.

### 3.2 TME Parameter - Parameter Attributes Data

At this level of analysis, in- or out-of-tolerance records are provided by TME parameter. The analysis procedure followed is identical to that described for parameter variables data, except that parameter tolerance limits are "externally" applied at the time calibration data are recorded. The flexibility of adjusting tolerance limits later to individual user requirements is lacking. For this level of analysis, care must be taken to ensure that data are grouped homogeneously with respect to tolerance limits applied during calibration.

Although parameter variables data provide greater flexibility in adjusting calibration intervals to user needs, considerable flexibility is also possible with parameter attributes data in that measurement reliability targets can be still applied by parameter. Parameter intervals and TME instrument intervals are determined as described in Section 3.1.

### 3.3 TME Model Number or Class - Instrument Attributes Data

At this level of analysis, in- or out-of-tolerance data are recorded at the TME instrument level; a TME instrument being considered out-of-tolerance if one or more of its parameters are out-of-tolerance. Parameter tolerance limits are provided externally (i.e., during calibration), and measurement reliability targets are usually applied at the model number or class level. Note that, as suggested by Eq. (3), if individual measurement reliability targets can be established by instrument user, calibration intervals based on model number or class data analysis may be computed and assigned by user at the individual TME serial number level.

Obviously, if calibration interval analysis is to rigorously uncover the measurement uncertainty growth process of the TME model number or class under study, data must be homogeneous with respect to procedures used, parameters calibrated and parameter tolerances.

# 4. Calibration History Data Requirements

Both administrative and technical data are needed for calibration interval analysis. Administrative data include information needed for identification, control and classification purposes. Technical data include quantities that comprise the dependent and independent variables used in time series construction, measurement reliability modeling and calibration interval computation.

The administrative and technical data elements required for calibration interval analysis are described in Sections 4.2 and 4.3. Before these elements can be used, certain considerations of data integrity must be addressed.

<sup>&</sup>lt;sup>8</sup> The simplest and possibly most useful method of determining TME instrument intervals from parameter intervals is described by Ferling [6].

### 4.1 Data Integrity Requirements

As is pointed out in Section 2, arriving at an appropriate calibration interval involves conducting an "experiment" to determine the applicable uncertainty growth process. Since we can't usually afford to conduct controlled experiments, we have to rely on data recorded as a result of routine calibrations. To ensure that these data are at the level of integrity needed to unambiguously determine uncertainty growth processes, the data need to be screened for homogeneity with respect to calibration procedure used, tolerances employed, etc. It is especially important to note that, if analysis is based on attributes data, the tolerance limits must be fixed for each parameter calibrated. Mixing data together from calibrations performed using different sets of tolerance limits equates to performing an "uncontrolled" experiment with a mixed bag of out-of-tolerance criteria. (Such mixing obscures the uncertainty growth process that calibration interval analysis attempts to model.) Similarly, if analysis is based on instrument attributes data, the set of parameters calibrated must also be fixed for each serial number item represented in the data.

### 4.2 Administrative Data Requirements

Administrative data are required for identification and classification of TME serviced, standards used, parameters calibrated, tolerances employed, procedures followed, etc. Administrative data are also needed to monitor and control calibration recall cycles. The administrative data elements required for calibration interval analysis and management are often found in existing calibration management systems; the following is a typical listing:

DATA ELEMENT	ANALYSIS LEVEL	PURPOSE
TME Serial or Tag Number	All	Data history compilation; Dog/gem ID; Recall interval assignment
TME Manufacturer	All	Data grouping
TME Model Number	All	Data grouping
TME Class	All	Data grouping *
TME Reliability Target	Model Number - Instr Attributes Data	Cal interval calculation
	Class - Instr Attributes Data	Cal interval calculation
TME Calibration Interval	All	Data grouping
Parameter Set Number	Model Number - Instr Attributes Data	Data grouping
	Class - Instr Attributes Data	Data grouping
Parameter Step Number	Parameter - Variables Data	Data history compilation
	Parameter - Attributes Data	Data history compilation
Parameter Tolerance Limit(s)	Parameter - Variables Data	Establish out-of-tolerance criteria
Parameter Nominal Value	Parameter - Variables Data	Establish out-of-tolerance criteria
Parameter Reliability Target	Parameter - Attributes Data	Parameter interval calculation
	Parameter - Variables Data	Parameter interval calculation
Cal Standard(s) Used	All	Data grouping
Procedure Number	All	Data grouping
Procedure Date	All	Data grouping

\* If TME are managed by Class

Serial or Tag numbers for each individual TME are needed to track times between calibrations and to identify individual items whose performance is superior (gems) or inferior (dogs) to the norm.<sup>9</sup> TME Manufacturer/Model and Class are needed to identify the homogeneous TME grouping under which data are to be accumulated for analysis. If analysis is to be performed at the TME parameter level, each parameter needs to be identified. If variables data are provided, the limit or limits of acceptable performance (tolerance limits) are needed to establish out-of-tolerance criteria. Identifying the standard(s) performing the calibration and the procedure used are needed to ensure that data are represented uniformly.

The element TME Calibration Interval is compared with the calculated resubmission time to evaluate whether the calibration service is of a routine nature (consistent with the conditions of the calibration interval "experiment"), reflects a user-detected problem, or indicates an inordinate period of storage.<sup>10</sup> This element can also be used to evaluate compliance with recall schedules, if desired.

### 4.3 Technical Data Requirements

Like their administrative counterparts, the technical data elements needed for calibration interval analysis are often available within existing calibration management systems. The needed technical data elements are as follows:

DATA ELEMENT	ANALYSIS LEVEL	PURPOSE
Date Received for Calibration	All	Resubmission time computation
Date Calibrated	All	Resubmission time computation
Date Returned to User/Storage	All	Resubmission time computation
As Found Condition	All	Evaluation of in- or out-of-tolerance status at end of interval
Action Taken	All	Evaluation of extent of renewal of TME item or parameter
As Left Condition	All	Evaluation of in- or out-of-tolerance status at beginning of interval

Resubmission time is the independent variable of the measurement reliability time series. The date each TME item was received for the current calibration (Date Received for Calibration) and the date of return of each TME item to the user following the previous calibration (Date Returned to User) are needed to compute resubmission time. If different from Date Returned to User, the element Date Calibrated can be used to evaluate shelf life uncertainty growth, if any. As Found Condition is required to evaluate whether the TME item or parameter is out-of-tolerance at time of calibration. If parameter variables data are recorded, As Found Condition is the recorded parameter value. Otherwise, it is an in- or out-of-

<sup>&</sup>lt;sup>9</sup> Dogs and gems are discussed later.

<sup>&</sup>lt;sup>10</sup> Sometimes the occurrence of a calculated TME resubmission time which is extreme relative to the scheduled resubmission time for the item indicates that a calibration has been performed which is missing from the item's calibration history data.

tolerance indication. Many organizations employ codes to indicate in- or out-of-tolerance status. Some facilities use a spectrum of codes to indicate degree of out-of-tolerance, if applicable.

The data element Action Taken is required to establish the extent of renewal of each calibrated TME or parameter. This is done to enable the measurement reliability modeling machinery to construct a beginning-of-period statistical probability density function (see Section 2.2) for measurement uncertainty growth modeling purposes. If variables data are provided, As Left Condition is the recorded parameter value prior to the return of the TME to use. If attributes data are taken, As Left Condition is usually "intolerance" but may in some circumstances be "out-of-tolerance."

### 4.4 Dogs and Gems

Using a statistical analysis methodology makes possible the identification of exceptionally strong or weak measurement reliability behavior at the parameter, serial number, model number and manufacturer levels [1,7,8]. From an analysis standpoint, identification of weak performers (dogs) is necessary for ensuring data homogeneity. From an administrative standpoint, identification of strong and weak performers at the model number and manufacturer levels can assist in procurement decisions. At the serial number level, weak performers may be considered for limited usage. Alternatively, strong serial number performers (gems) may be selected as reference or transfer standards.

### 4.5 Out-of-Tolerance Feedback Requirements

Regardless of the level of analysis, many organizations require that variables data be provided on TME parameters which are found to be out-of-tolerance. These data are reported by serial number and parameter to TME users to enable an assessment of the use of the out-of-tolerance parameters on prior testing of end item attributes. Methods for evaluating TME out-of-tolerance parameter data to determine impact on end item performance are currently under development [9].

# 5. Data Structures

The data elements necessary for statistical calibration interval analysis are often found in the existing data structure of calibration management programs. A data structure of the type expected to be encountered in modern calibration support programs is described in this section. The data structure consists of three major classes of files; namely Definitional, Operational, and Archival.<sup>11</sup>

### 5.1 Definitional Files

The Definitional files define the TME equipment, the classes, the procedures, the parameter sets, the recommended standards, the departments, and the employees. There are 11 Definitional files.

Even though establishing these Definitional files may require considerable effort, they are essential to ensure data with sufficient integrity and homogeneity to permit meaningful statistical interval analysis.

<sup>&</sup>lt;sup>11</sup> The data structure described in this paper comprises only a subset of a total calibration management data structure. The subset is that which contains data elements needed for statistical calibration interval analysis.



Figure 5. Example Data Structure for Calibration Program Management. The general data structure shown contains the elements necessary for calibration interval management.

#### CLASS FILE

The Class File is only required if interval analysis will be done by TME class (see Section 3.3). There is only one record on the Class File for each equipment class. This record describes the class and specifies the reliability target, the reliability model, and the model coefficient vector for the class.

As calibration data are analyzed for the class, additional data elements are computed and stored on this file for easy reference including the number of items in the class, the measurement reliability index and MTBF for the class, and other statistical quantities.

For the sake of data integrity, CLASS FILE data elements are retained for the previous analytic period as well as the current analytical period.

#### DATA ELEMENTS: Class ID Class Description

**Previous** (For Reference and Data Security): Class Measurement Reliability Target Number of Items in Class Class Measurement Reliability Index Lower Measurement Reliability Confidence Limit ( $0\% \le R$ ) Upper Measurement Reliability Confidence Limit ( $R \le 100\%$ ) Class Calibration Interval Number of Items with Low Measurement Reliability Number of Items with High Measurement Reliability Class MTBF Class Reliability Model

Class Reliability Model Coefficient Vector

#### Current:

Class Measurement Reliability Target Number of Items in Class Class Measurement Reliability Index Lower Measurement Reliability Confidence Limit ( $0\% \le R$ ) Upper Measurement Reliability Confidence Limit ( $R \le 100\%$ ) Class Calibration Interval Number of Items with Low Measurement Reliability Number of Items with High Measurement Reliability Class MTBF Class Reliability Model Class Reliability Model Class Reliability Model Coefficient Vector **Other Data as Desired** 

#### MANUFACTURER/MODEL FILE

The Manufacturer/Model File is required if interval analysis will be done by either TME class or by TME model number (see Section 3.3).

There is one record on the Manufacturer/Model File for each equipment manufacturer/model. This record describes the manufacturer/model and specifies the reliability target, the reliability model, and the model coefficient vector for the manufacturer/model.

As calibration data are analyzed for the manufacturer/model, additional data elements are computed and stored on this file for easy reference including the number of items in the manufacturer/model, the measurement reliability index for the manufacturer/model, the new calibration interval for the manufacturer/model, the MTBF for the manufacturer/model, and other statistical quantities.

For the sake of data integrity, MANUFACTURER/MODEL FILE data elements are retained for the previous analytic period as well as the current analytic period.

#### DATA ELEMENTS:

#### <u>Manufacturer</u> <u>Model</u> Model Description Class to Which Model Belongs

Previous (For Reference and Data Security):Model Measurement Reliability TargetNumber of Items in ModelModel Measurement Reliability IndexLower Measurement Reliability Confidence Limit ( $0\% \le R$ )Upper Measurement Reliability Confidence Limit ( $R \le 100\%$ )Model Calibration IntervalNumber of Items with Low Measurement ReliabilityNumber of Items with High Measurement ReliabilityModel MTBFModel Reliability ModelModel Reliability Model Coefficient Vector

#### Current:

Model Measurement Reliability Target Number of Items in Model Model Measurement Reliability Index Lower Measurement Reliability Confidence Limit ( $0\% \le R$ ) Upper Measurement Reliability Confidence Limit ( $R \le 100\%$ ) Model Calibration Interval Number of Items with Low Measurement Reliability Number of Items with High Measurement Reliability Model MTBF Model Reliability Model Model Reliability Model Coefficient Vector

#### Other Data as Desired

#### MANUFACTURER FILE

The Manufacturer File is required to validate the manufacturer ID on the Manufacturer/Model File and on the Instrument File. There is one record on the Manufacturer File for each equipment manufacturer.

#### DATA ELEMENTS: <u>Manufacturer</u> Manufacturer Name Other Data as Desired

#### INSTRUMENT FILE

There is one record on the Instrument File for each piece of TME equipment. This record describes the Instrument and the class, manufacturer, and model to which the instrument belongs.

This record also contains the serial number of the instrument, the instrument usage type, the departments which "own" and which "use" the instrument, the calibration due date and interval, the calibration procedure which is used, the parameter set number which is used, the standards which are used, the reliability target, MTBF, number of times calibrated, number of times in-tolerance, the calculated reliability index, and the Q-classification (dog/gem).

The calibration procedure is required in order to ensure that analysis is performed on statistically homogeneous sets of instruments. If data will be captured and analyzed at the parameter level, then the procedure must specify these parameters.

#### DATA ELEMENTS:

Instrument ID Class Manufacturer Model Serial Number Equipment Usage Type (TME, Reference Std., Primary Std, etc.)

**Owning Department** (To address Recall Report or Prompt) **Using Department** (To monitor usage conditions)

Calibration Due Date Calibration Interval

**Procedure** (Determines which Instruments to analyze) **Parameter Set Number** (Defines the Parameters to be calibrated and Tolerances to be used for the Instrumer **Standards** (Defines Standards required by the Procedure)

#### Measurement Reliability Data:

from Model: Measurement Reliability Target MTBF Number of Times Calibrated Number of Times In-Tolerance Measurement Reliability Index (Calculated) Q-Classification (Gem/Dog/Normal)

#### Other Data As Desired

#### DEPARTMENT FILE

The Department File is required to validate the Owning and Using Departments on the Instrument File. There is one record on the Department File for each department.

DATA ELEMENTS: <u>Department ID</u> Department Description Other Data as Desired

#### EMPLOYEE FILE

The Employee File is required to validate the Technician ID responsible for the calibration on the Calibration File. This file might also be used to track technician certification to ensure that the technician was "qualified" to perform a given calibration. There is one record on the Employee File for each employee.

DATA ELEMENTS: <u>Employee ID</u> Name Other Data as Desired

#### PROCEDURE FILE

The Procedure File validates the Procedure Number on the Instrument File. A procedure can be "generic" and apply to several different parameter sets. There is one record on the Procedure File for each calibration procedure.

DATA ELEMENTS: <u>Procedure Number</u> Procedure Description Other Data as Desired

#### PARAMETER SET MASTER FILE

The Parameter Set Master File is required if variables or attributes will be captured or analyzed at the parameter level.

The Parameter Set Master File validates the Parameter Set Numbers on the Instrument File and on the Parameter Data File. The Parameter Set Master File defines the specific set of parameters which will be captured and evaluated for each instrument. This architecture permits "generic" procedures with "specific" parameter sets, sometimes called "data sheets."

#### DATA ELEMENTS:

<u>Parameter Set Number</u> (Defines the Parameters to be calibrated and Tolerances to be used for the Instrument application) Parameter Set Description Other Data as Desired

#### PARAMETER DATA FILE

The Parameter Data File is required if variables or attributes data will be captured or analyzed at the parameter level. The Parameter Data File describes each parameter step and defines the nominal and tolerance values for the variable.

#### DATA ELEMENTS:

Parameter Set Number Parameter Step Number Parameter Step Description Nominal Parameter Value Low Tolerance Limit High Tolerance Limit Other Data as Desired

#### **RECOMMENDED STANDARDS FILE**

The Recommended Standards File is optional. It specifies the standards that should be used for a given calibration procedure. The standards might be specified as specific instrument IDs or with manufacturer/model codes for a generic standard.

DATA ELEMENTS: <u>Procedure Number</u> <u>Standard Instrument ID</u> (For Specific Standard) or <u>Manufacturer</u> (For "Generic" Standard)

#### <u>Model</u> Other Data as Desired

#### VENDOR FILE

The Vendor File is required to validate the Vendor ID on the Calibration File and Repair File. There is one record on the Vendor File for each vendor to whom equipment might be sent.

DATA ELEMENTS: <u>Vendor ID</u> Vendor Name Other Data as Desired

#### 5.2 Operational Files

The Operational files define the events, results, and data for each calibration or repair. There are five Operational files.

#### TRACKING FILE

The Tracking File logs the progress of each instrument through the calibration and repair process. The Tracking File identifies WHEN each step was performed and by WHOM.

DATA ELEMENTS:
Instrument ID
Service/Work Order Number
or
Service Date
Dates:
Received for Calibration
Calibrated
Returned to User/Storage
Other Data as Desired

#### CALIBRATION FILE

The Calibration File stores the calibration results, including the calibration procedure used, the responsible technician, the standards used, the new due date, the interval, and the instrument attribute.

DATA ELEMENTS: Instrument ID Service/Work Order Number or Service Date Calibrating Technician Procedure Number Parameter Master Standards Previous:

Calibration Due Date Calibration Interval Instrument Attributes Data (In-/Out-of-Tolerance)

#### **Current Calibration:**

Date Received for Calibration Date Calibrated Date Returned to User/Storage Instrument Attributes Data (In-/Out-of-Tolerance)

#### VARIABLES FILE

The Variables File stores the AS FOUND, ACTION TAKEN and AS LEFT readings for each parameter. It also stores the parameter attribute value or code.

DATA ELEMENTS: Instrument ID Service/Work Order or Service Date Parameter Set Number Parameter Step Number "As Found" Reading "As Left" Reading Action Taken Parameter Attributes Data (In-/ Out-of-Tolerance)

#### STANDARDS FILE

The Standards File stores the instrument ID of the standards used during a calibration. These standards determine the forward and reverse traceability for each calibration.

#### DATA ELEMENTS: <u>Instrument ID</u>

Service/Work Order or Service Date Parameter Set Number Parameter Step Number Standard Instrument ID Standard Calibration Due Date (Traceable to a Specific Calibration) Standard Last Calibrated Date Calibration Process Uncertainty Estimate Other Data as Desired

#### **REPAIR FILE**

The Repair File stores the repair actions performed and the replacement parts used during a calibration or repair.

DATA ELEMENTS: <u>Instrument ID</u> <u>Service/Work Order Number</u> or <u>Service Date</u> <u>Other Data as Desired</u>

### 5.3 Archival Files

The Archival files store the Operational data for completed calibrations and repairs. There are five Archival files. The Archival Files have the same structure and labeling as the Operational Files.

# 6. Calibration Data Processing

A complete description of the processing of a statistical calibration interval system is beyond the scope of this paper. Instead, two processes, "recording calibration file data" and "TME MTBF calculation" are provided to illustrate the use of some of the data elements identified above and to demonstrate how data are grouped for homogeneity. Several hundred such processes are involved in recording, reducing, conditioning, storing and analyzing calibration data in the course of determining optimal calibration intervals.



**Figure 6. Recording Calibration File Data.** Shown are the steps in recording data in the Calibration File for calibration interval management based on TME attributes data. In such cases, an item of TME is considered out-of-tolerance (OOT) if one or more of its parameters is OOT. The sequence portrayed assumes that OOT parameters are adjusted. Provision is also made for adjustment of in-tolerance parameters, if performed.



**Figure 7. TME MTBF Calculation.** Calculation of the MTBF (mean time between out-of-tolerances or "failures") for analysis done at the TME Model Number - Instrument Attributes Data level. Note that a different MTBF is calculated for each homogeneous calibration data set. For this level of analysis, homogeneous calibration sets are distinguished by manufacturer/model, parameter set, calibration procedure and tolerances used.

# 7. References

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