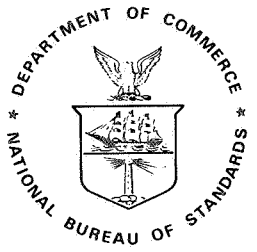

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Measurement Assurance Programs Part I: General Introduction

Measurement Assurance Programs
Part I: General Introduction

Brian Belanger

Office of Physical Measurement Services
National Measurement Laboratory
National Bureau of Standards
Washington, DC 20234

U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, Secretary
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, Director

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Foreword

This two-part guide has been written in response to numerous inquiries concerning the use of Measurement Assurance Program (MAP) Services offered in conjunction with the Calibration Services of the National Bureau of Standards. MAP Services differ from the usual Calibration Services because they focus on the quality of measurements being made by the participant rather than just the properties of the participant's instruments or standards. The services are offered as an adjunct to the user's own measurement control programs and are designed to help a laboratory quantify the uncertainty of its measurements relative to national standards. MAP services represent a new approach to "calibration" and this publication presents the rationale for their use.

This guide consists of two parts published separately:

- Part I - A General Introduction, authored by Brian C. Belanger, Chief, Office of Physical Measurement Services.
- Part II - Development and Implementation, authored by Carroll Croarkin, Statistical Engineering Division.

Part I of this guide is intended as a general introduction to MAPs. It is not intended as a specification for the kind and magnitude of the effort required to ensure that measurements are adequate for their intended use. It is intended to provide enough detail on NBS MAP Services to help potential users decide whether or not such services can play a useful role in their measurement activities. The first part of this guide gives illustrations of proven approaches to measurement control to assist the reader in constructing or upgrading an internal quality control program.

Part II is concerned with the development and implementation of MAPs. Particular emphasis is placed on principles for statistical analysis and interpretation of MAP data, including characterization of measurement errors, use of control charts and specific examples of MAPs in process.

Users of these MAP Services must determine what constitutes adequate measurement quality control for their applications. Not every laboratory will find it necessary or desirable to use NBS Measurement Assurance Program Services. This guide will enable users of NBS MAP Services to ensure that the services are utilized more effectively.

George A. Uriano
Director
Measurement Services
National Bureau of Standards
April 15, 1984

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Measurement Assurance Programs

Part I. General Introduction

1. Introduction and Purpose

This is the first of a two-part guide. This part explains the concept of measurement quality assurance, describes the services offered by the National Bureau of Standards (NBS) to support measurement quality assurance, and provides information concerning the benefits that could accrue to users of NBS Measurement Assurance Program (MAP) services and those employing measurement quality control procedures. Part II describes the statistical techniques used to implement measurement assurance programs.

It is useful to distinguish between a Measurement Assurance Program (MAP) and NBS MAP services. A MAP is the measurement quality assurance program implemented by the participant outside NBS to ensure accurate measurements relative to national standards. NBS MAP services are offered by the Bureau to aid in the achievement of measurement quality control in the participating laboratory and to link the measurements in that laboratory to national standards.

This publication (the first part of the guide) does not attempt to cover the detailed technical material needed to establish and maintain a MAP in any of the technical areas mentioned. A bibliography is provided for the reader interested in understanding the MAP approach as applied to any specific technical area. A glossary of terms related to measurement assurance is provided to help the reader understand this and other publications on measurement assurance.

The MAP concept is still evolving. MAP services that NBS currently offers have been developed somewhat independently of each other; consequently, differences exist among these services. As the approach to measurement quality control evolves, both the concept and its application will probably change. NBS MAP services may become more uniform in their approach and design, and new MAP services will certainly incorporate the best features of existing services. Thus, it is important that NBS receive feedback from users of its MAP services.

The MAP approach to measurement quality control (QC) or quality assurance (QA) for physical measurements is not particularly unique*. Those familiar with the principles of QC and applied statistics will recognize that most, if not all, of the features of a MAP are tools that are well known in the QA field. In fact, to a great extent, a MAP can be thought of as statistical quality control procedures developed many years ago by Shewhart and others applied to a measurement process**. Similar methods have been used to ensure the accuracy of industrial chemical processes, clinical laboratory and biological laboratory measurements, etc. The essential feature of a MAP is that it focuses on the whole physical measurement process: the operator, the environment, the methods, in

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* The terms "quality control" and "quality assurance" are defined in the glossary.

** The term "measurement process" is defined in the glossary.

addition to the instrument. The purpose of a MAP is to establish relative to national standards the uncertainty of the measurements being made, and to monitor that uncertainty on a continuing basis to ensure that the measurements are sufficiently accurate for their intended application.

For those who want only an "executive summary" of the subject, the next section consists of answers to the 19 questions most frequently asked about MAPs.

2. The Nineteen Most Frequently Asked Questions About MAPs: An Executive Summary

1. WHAT IS A MAP?

A MAP is a quality assurance program for a measurement process that quantifies the total uncertainty of the measurements (both random and systematic components of error) with respect to national or other designated standards and demonstrates that the total uncertainty is sufficiently small to meet the user's requirements*.

2. HOW DOES AN NBS MAP SERVICE DIFFER FROM AN NBS CALIBRATION SERVICE?

NBS MAP services focus on the quality of measurements being made in the participating laboratory rather than on the properties of the participants instruments or standards. Conceptually, participation in a MAP service can be thought of as a way of "calibrating" the entire laboratory.

In an NBS calibration, the customer's device or standard is sent to NBS to be calibrated. When the device or standard is returned to the customer, the customer receives an NBS test report containing measured value(s) of the standard and an associated measurement uncertainty(s) relative to national standards. The uncertainty reported on an NBS calibration is a measure of the quality of the NBS calibration process and is not a property of the instrument or standard or the customer's measurement system.

The proper use of a calibrated standard can result in accurate measurements in the customer's laboratory. However, if the operators are not sufficiently skilled, if the environmental conditions of the laboratory differ from those at NBS, if unsound measurement procedures are used, or if other problems (known or unknown) exist, then the measurements actually made in the customer's laboratory may not be nearly as accurate as the uncertainty of the NBS-calibrated standard would, in principle, permit. Without some comparison between the NBS measurement process and the customer's, no unequivocal statement can be made about the actual accuracy of the laboratory's measurements.

The MAP service quantifies the total uncertainty of the participant's measurement process. In order to establish this uncertainty, it is necessary for the participating laboratory to

* The terms uncertainty, random error, and systematic error are defined in the glossary.

have an ongoing measurement control program. In such a program measurements are repeated on one or more stable standards in order to estimate the random error associated with the partcipating laboratory's measurement process.

In a typical MAP service, a stable artifact (or set of artifacts) referred to as a "transport standard,"* is measured at NBS and sent to a participating laboratory for measurement by that laboratory. The value of the transport standard is normally unknown to the participant. Following measurements by the participant, the transport standard is returned to NBS for remeasurement. The NBS data and the data from the participating laboratory are then analyzed, and a test report is sent from NBS to the participant stating the offset of the participating laboratory's measurement process from national standards and the total uncertainty of the participant's calibration process.

The total uncertainty of the participating laboratory's measurement process reflects both the random error (a measure of the reproducibility, precision, or within-laboratory variability), and the systematic error (any uncorrected bias or offset of the measurements relative to national or other designated standards).

3. ISN'T IT POSSIBLE TO ACHIEVE A HIGH LEVEL OF ACCURACY BY USING NBS CALIBRATION SERVICES INSTEAD OF NBS MAP SERVICES?

Yes, but experience has disclosed that some users of NBS calibration services have had longstanding measurement problems that remained undiscovered until they participated in a MAP. It is certainly possible for a laboratory to achieve a high level of accuracy without using NBS MAP services if standards calibrated by NBS are used to assess the offset of the measurement process from the nationally accepted reference base and if rigorous measurement quality assurance procedures described elsewhere (see Part II of this guide) are used.

Occasionally participation in a MAP discloses that a laboratory is performing more accurate measurements than had been assumed. New MAP participants often find, however, that their measurement uncertainty is not as good as they had thought. Participation in a MAP, often improves the laboratory's precision or accuracy from initial values. Because the measurement assurance regimen requires that measurements be made on an on-going basis following consistent procedures, some facility may be acquired in following the measurement procedures that did not previously exist. In other cases, flaws in the measurement methods or environmental conditions had gone unnoticed when the laboratory relied only on NBS calibrations.

4. HOW DOES A MAP SERVICE DIFFER FROM A "ROUND-ROBIN" INTERCOMPARISON?

Round-robin** intercomparisons of standards are often used to reveal systematic errors and measurement inconsistences among laboratories,

* Defined in the glossary.

** Round-robin is defined in the glossary.

but a MAP is more than a round-robin intercomparison. In order to take full advantage of a MAP service the participant is expected to make measurements on a continuing basis, using an in-house check standard between the times that the transport standard is measured, to provide assurance that the measurement process has not gone out of control since the last measurement on the NBS transport standard.

5. HOW MANY MAP SERVICES DOES NBS CURRENTLY OFFER?

NBS currently (1984) offers eight MAP services in the following areas:

- Mass
- Gage Blocks (pilot program)
- DC Voltage (standard cells)
- Capacitance
- Resistance
- Electric Energy (watthour meters)
- Temperature (resistance thermometry)
- Laser Power and Energy

Other MAP services are being developed in areas such as microwave power and spectrophotometry. Chapter 5 provides additional details.

6. HOW MUCH DOES IT COST TO USE NBS MAP SERVICES?

The cost of the NBS MAP service depends on the service and how frequently it is used. The actual cost per year to the participant may average less than the currently advertised MAP service cost since it may not be necessary to use the service annually. Also, the organization may choose to join with others in a group arrangement (described in Chapter 6) to reduce the cost. The fees for NBS MAP services change from time to time; thus it is advisable to check with the point of contact listed in NBS Special Publication 250 to determine the current price*.

In addition to the NBS fee, participation in a MAP may involve costs associated with the purchase of additional equipment and/or additional staff time in the participating laboratory, particularly if the laboratory has not previously instituted quality control procedures in its measurement process.

7. IF I UTILIZE AN NBS MAP SERVICE, WHAT DO I HAVE TO DO BESIDES MAKE MEASUREMENTS ON THE TRANSPORT STANDARD?

It is important to recognize that NBS does not audit or regulate metrology laboratories as part of the MAP service. Whatever steps are taken by a laboratory participating in a MAP to improve its measurement process are taken voluntarily.

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*Kieffer, L. J. ed. Calibration and Related Measurement Services of the National Bureau of Standards, Natl. Bur. Stand. (U.S.) Spec. Publ. 250; (new edition issued every two years). An Appendix to SP250 (current price list) is published by NBS every six months.

Although the transport standard calibrated by NBS is indispensible in the operation of a MAP, participation also requires making measurements on in-house check standards on a continuing basis to estimate the random error and to make sure that the measurement process remains in a state of statistical control*. Unless the participating laboratory has a measurement control program to monitor its own measurement process parameters, there is little point in participating in a MAP service.

MAP participants may also have to perform some data analysis.

8. DO I HAVE TO BE AN EXPERT STATISTICIAN TO BE ABLE TO PARTICIPATE IN A MAP?

No, all one needs is "statistical awareness," that is, an appreciation of the rationale for the statistical techniques. However, the more one knows about statistics, the better one will be able to interpret and utilize the results. The amount of statistical manipulation of data by the MAP participants varies among the existing NBS services from essentially none to a considerable amount. In general though, all that is required is that measurement instructions be followed and data reported in a specified format. The amount of data analysis done by NBS as compared with that done by the participants is negotiable. For many MAPs, the data can be analyzed on a programmable calculator. NBS can provide participants with tapes or listings of many of the programs. (See Chapter 5 for details.)

An individual with some knowledge of statistics will be able to understand most of the MAP methodology used by NBS in the data analysis. Someone with a more extensive knowledge of statistics will be able to appreciate all of the subtleties of the method and may be able to see ways to utilize the data more effectively. NBS staff are eager to have each participant succeed and will provide consulting help whenever necessary to explain the data analysis and methodology.

9. DOES A MAP SERVICE PROVIDE THE TRACEABILITY TO NATIONAL STANDARDS REQUIRED FOR COMPLIANCE WITH MILITARY SPECIFICATIONS OR REGULATORY DOCUMENTS?

Successful participation in a MAP provides excellent evidence of traceability to national standards. Users of MAP services receive a test report from NBS stating their measurement uncertainty.

NBS does not require traceability of anyone, nor does NBS have legal responsibility for determining whether or not a particular organization has adequately demonstrated traceability to national standards. This is the responsibility of auditors from the organization requiring traceability (e.g., the Defense Contracts Administrative Service, the Nuclear Regulatory Commission, etc.)

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* "State of statistical control" is defined in the glossary.

Traceability to NBS has traditionally been achieved by obtaining an NBS calibration of customer-owned standards. Prior to the introduction of MAP services, auditors generally considered an organization to have met the requirements for traceability if documentation could be produced to show that its standards had been calibrated "traceable to NBS." When MAP services were first introduced, some auditors who were unfamiliar with the approach questioned the acceptability of the MAP reports as evidence of traceability, since the MAP participant's standards were not calibrated by NBS. The problem now seems to be disappearing as auditors come to appreciate that a MAP is usually a more effective kind of traceability than an NBS calibration. This is discussed in more detail in Chapter 4.

10. WHAT EXACTLY DO I GET FROM NBS WHEN I REQUEST A MAP SERVICE?

Typically, the customer receives from NBS (usually by air freight) one or more transport standards that have been carefully measured before leaving NBS. The standard is measured a prescribed number of times by the participant and returned along with the data to NBS. NBS remeasures the standard and then provides a test report stating the offset of the participant's measurement results from NBS and the associated uncertainty. Usually, NBS provides some or all of the data analysis. NBS also provides technical publications and/or oral guidance on theoretical considerations, measurement control techniques, and recommended practices for the various measurements. When a problem arises in the participating laboratory, NBS will also provide (within reasonable limits) consultation to uncover and correct the problem. (If the customer does not already employ measurement quality control practices, NBS will provide material explaining how to institute such practices, before sending the transport standard.)

11. WHAT IS A REGIONAL OR GROUP MAP?

This new approach to disseminating MAP Services is described in detail in Chapter 6. Briefly, a regional or group MAP is a MAP wherein cooperating laboratories interact with NBS as a group. Generally one laboratory agrees to serve as the "pivot" laboratory, providing the principal point of contact with NBS. The out-of-pocket cost to the participants in a group MAP is reduced by sharing the cost of the transport standard from NBS. Faster resolution of measurement problems and other benefits may also result from group participation.

Those considering MAP participation on a regional basis are encouraged to call or write to the chairman of the Measurement Assurance Committee of the National Conference Standards Laboratories (See Chapter 8). The prospective participant can then be put in touch with other similar laboratories who have participated in group or regional MAPs, and learn of their experiences.

12. HOW DO MAP SERVICES RELATE TO LABORATORY ACCREDITATION?

NBS does not presently accredit calibration laboratories for all types of calibrations, although some limited scope calibration accreditation programs are receiving consideration under the auspices of the National Voluntary Laboratory Accreditation Program, NVLAP*. Ideally, accreditation should be based on a laboratory's ability to demonstrate that its measurements have uncertainties relative to national standards less than some specified limit. Successful participation in a MAP can provide important evidence of competence required for laboratory accreditation by any organization that chooses to accredit laboratories.

13. WHAT SPECIAL PRECAUTIONS NEED BE TAKEN WHEN MAKING MEASUREMENTS ON THE NBS MAP STANDARD?

The MAP service is designed to assess the quality of the laboratory's calibration process, hence it is essential that the measurements on the transport standard reflect the normal operating conditions of the laboratory. Because future assignments of values to items calibrated by the laboratory will depend on these measurements, the laboratory's measurement system must be operating in a state of statistical control when the comparison with the transport standard takes place. To ensure process control operational and statistical tests or checks should be included in the measurement scheme when the transport standard is measured by the participant. Such checks may or may not be part of the instructions issued by NBS. Upon request, NBS can provide guidance on suitable checks where such checks are not explicitly included in the instructions.

Strictly speaking, the offset identified by the exchange with NBS applies only to laboratory conditions that are identical to test conditions. For example, optical systems with visual eyepieces are operator-dependent, requiring separate tests for each operator, and resulting in individual offsets or corrections for each operator. Extension of the uncertainty statement to varied laboratory conditions is valid only insofar as the error estimate has been structured to include these variations.

14. MUST A MAP BE OPERATED AT STATE-OF-THE-ART ACCURACY?

No, one must distinguish between the MAP concept and NBS MAP services. NBS MAP services are generally intended to be at state-of-the-art accuracy, but the MAP concept can be applied at any level of accuracy.

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* For more information on the NVLAP accreditation program, write to the Office of Laboratory Accreditation at NBS.

15. CAN LABORATORIES OUTSIDE THE U.S. PARTICIPATE IN MAPS?

Under very special circumstances, this may be possible, but requests for such participation must be reviewed on a case-by-case basis. MAP services are not normally provided to non-U.S. requestors. Technical constraints on the long-distance transporting of standards may also limit participation from outside the U.S. A foreign laboratory should transmit its request for NBS MAP services to the NBS Office of International Relations along with an explanation of why measurement services available in its own country are not adequate. To expedite the decision on the request, a letter from the national standards laboratory or embassy of the country should accompany the request. This letter should indicate that the government of the requesting country has no objection to NBS providing such service.

When NBS can grant the request, the cost to the foreign participant will exceed that to U.S. participants due to the additional costs of communication and shipping.

16. HOW CAN THE COST OF A MAP SERVICE WHICH MAY EXCEED THAT OF AN NBS CALIBRATION BE JUSTIFIED TO COST-CONSCIOUS MANAGEMENT?

The nature of the justification will vary depending on the mission of the laboratory. The MAP service provides an unambiguous mechanism for proving the competence of a laboratory in performing accurate measurements relative to national standards.

To quantify the benefits of a MAP, the lab manager must ask, "What is the economic penalty associated with having measurements of inadequate accuracy and/or unknown uncertainty?" Inadequate measurement capability in industry often leads to "good" products being scrapped or submitted for rework and "bad" products being accepted. It may lead to costly disputes between a firm and its suppliers or its customers. The resulting economic penalties can often be estimated. One can also estimate the costs associated with having to overdesign a product to meet a tight specification because of the inability to accurately measure its actual properties.

While a MAP service generally costs more than the corresponding calibration service on a one-time basis, one should consider the cost differential from a long term perspective. After participating in a MAP for a period of time, most participants find that they can extend the intervals between transfers from NBS so that the NBS MAP service is used less frequently than the corresponding calibration service. Thus, the use of MAP services may be more expensive in the short term, but less expensive in the long term.

17. HOW WOULD AN AUDITOR CHECK A LABORATORY UTILIZING NBS MAP SERVICES TO ENSURE THAT ADEQUATE TRACEABILITY WAS BEING MAINTAINED?

The relationship between MAPs and traceability is discussed in Chapter 4. The procedure for auditing a laboratory utilizing NBS