

Laboratory Quality Manual

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Change History

Change History				
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H	5/17/04	2.6 Changed traceability from “national or international standards” to “SI units”	BP	BP
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K	6/27/2006	Revised explanation of Appendix 2 and related Section 1.3.	LP	BP
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P	2/11/10	Updated para 1.0 Org chart to reflect changes in responsibility and authority.	RJH	SC

1.0 Management Requirements

1.1 Organization and Management

Bios International is an ISO 17025-accredited laboratory located in Butler, NJ. Within this facility, all Bios International products are manufactured, and associated calibration services performed, under the direction of the President. From this point forward, Bios International's calibration operations will be referred to as "Bios International," "the organization," "the laboratory," or simply "we" or "our."

Bios International maintains a clearly documented organizational structure, defining the authority, interrelation, and responsibilities of personnel throughout the laboratory. Our managerial staff is given the authority and resources to effectively operate the laboratory, train personnel, satisfy customers, and meet all quality requirements.

Our organizational structure is designed in such a way as to prevent – and where this fails, minimize and then correct – breaches of calibration integrity. To this end, management diligently monitors calibration activities to ensure that they are accurate and conducted honestly and in good faith. Further, laboratory personnel do not interact with or involve customers and are isolated from undue pressures that may adversely affect calibration integrity, not allowing financial issues, customer influences, company deadlines, and unforeseen circumstances influence calibration accuracy. If, at any time, a laboratory employee believes there is undue influence on calibration personnel, he is directed to report the situation to the President. If calibration integrity is ever in doubt due to unforeseen circumstances, we will cease calibration activities until the situation is resolved.

The following job descriptions and associated organizational chart define our organizational structure. To further supplement this manual, top management members maintain and update employee job descriptions for all personnel.

1.1.1 Chairman and CEO

Responsible for the financial, marketing, allocation of resources, and strategic planning of the company.

1.1.2 President,

Responsible for the successful operation of the company and implements the company's financial, marketing and strategic plan.;

1.1.3 Chief Metrologist, ISO 17025 Technical Manager

Is responsible for generating the laboratory quality policy and additionally, the Technical Manager (as defined per ISO 17025), and is responsible for determining the technical adequacy and accuracy of our laboratory's calibration methods and tests. He is called upon to suggest resources, assess tests, make technical determinations, and troubleshoot calibration activities.

1.1.4 Manager, Production

The Manager of Production reports to, and has direct access to, the President. He is responsible for overseeing the generation and implementation of production processes, the day-to-day operations of the laboratory, and defining technical requirements used in the laboratory and in production. He is also responsible for Production personnel qualifications appropriate to their assigned duties.

1.1.5 VP Engineering

The VP of Engineering reports to the President, and is responsible for conducting design and engineering activities, in addition to overseeing the engineering departments. The VP of Engineering troubleshoots instrument calibration and engineering issues. The VP of Engineering acts as ISO 17025 Technical Manager, when needed.

1.1.6 Manager, Sales and Customer Service

Responsible for all direct sales activities and customer service and reports to the President.

1.1.7 ISO 17025 Quality Manager

The ISO 17025 Quality Manager is responsible to interact with NVLAP and all issues dealing with accreditation and oversee the maintenance of the ISO 17025 program. He is responsible for creating, documenting, implementing and monitoring the Management System and its operation, and reporting the status and effectiveness of the Management System to the President. He also ensuring its implementation at all levels, overseeing the operation of the Management System, provides a commitment to customer satisfaction, ensures that employees are competent in there assigned tasks, and monitors the management system as part of the Management Review process. The QMS Auditor acts as the ISO 17025 Quality Manager in the ISO 17025 Quality Manager's absence.

1.1.8 Controller, Administration, and Human Resources

Responsible for reporting the financial activity of the company to the Chairman/CEO and President. Handles all administrative and Human Resources activities and reports to the President and Chairman/CEO.

1.1.9 Managerial Staff and Supervisors

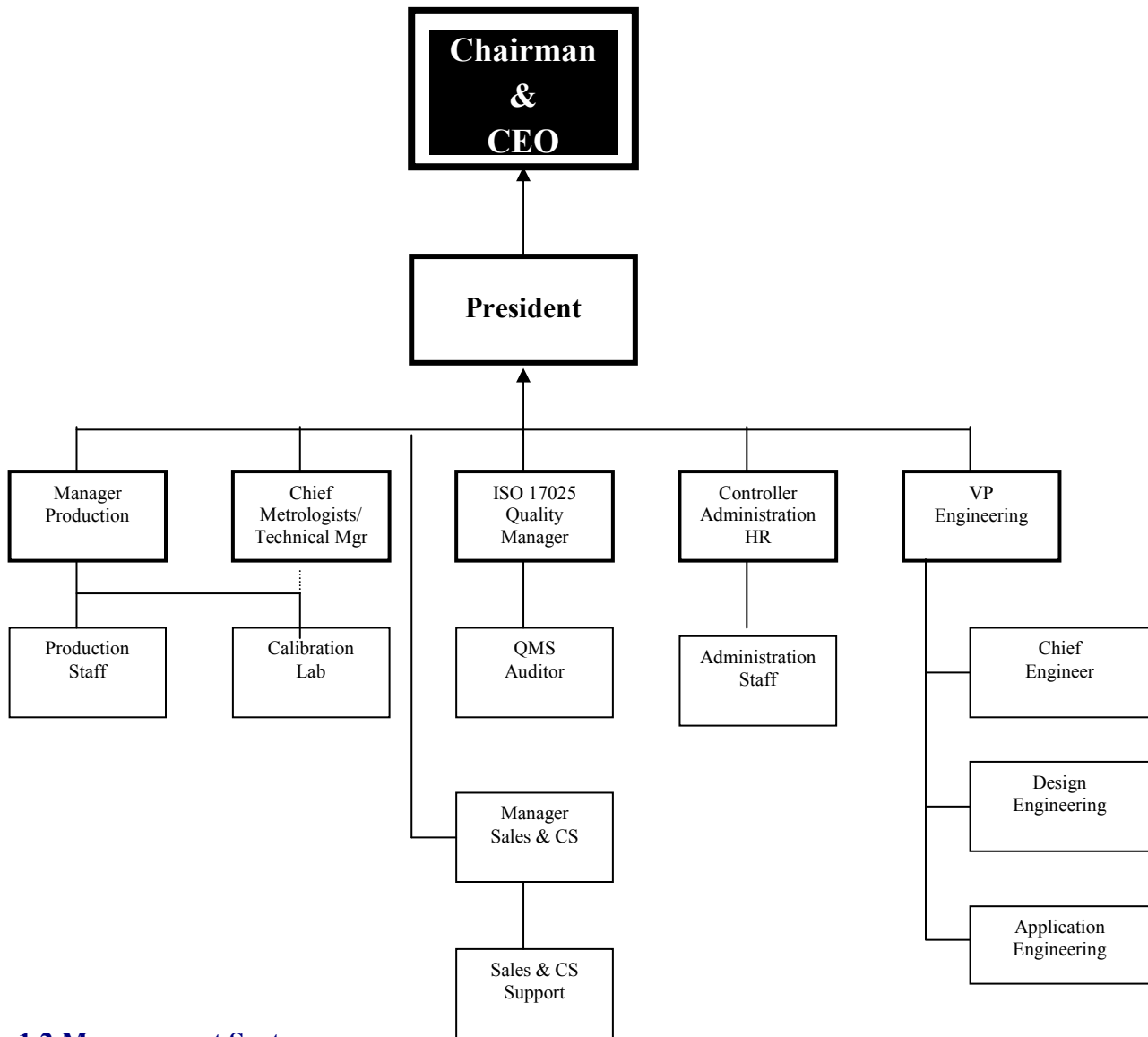
In addition to the President, VP Engineering, and Production Manager, other managers are likewise part of the Managerial Staff, and as such, responsible for the organization, planning, and overall operations of their departments. The Managerial Staff respects our management system and operating procedures, and in this spirit they maintain and manage personnel so as to ensure they are qualified, trained properly, perform work adequately, follow all procedures, and keep customer information and intellectual property confidential and protected at all times.

The Managerial Staff has a sufficient supervisory support staff, including qualified laboratory supervisors to provide all needed technical expertise. Supervisors work with managers to ensure that work is completed effectively and in compliance with relevant documentation, and that nonconformances are documented to help guard against future instances. The President periodically reviews staff allocation and requirements as a function of Management Review and assigns additional staff as necessary.

1.1.10 Personnel Proficiency

Bios International maintains an ongoing program of staff proficiency testing and training whenever needed, reflected in our staff members' training records. Our management system's Goals and Objectives (QS02-05) are periodically reviewed with all staff members, and each member's impact on our management system discussed. To this end, we empower personnel by encouraging and providing open lines of communication to the Managerial Staff to discuss any aspect of the management system. All of this helps to maintain personnel proficiency, consequently assuring that all calibrations, tests, actions, and other activities and requirements noted within this manual are conducted in accordance with documented procedures.

1.1.9 Organizational Chart



1.2 Management System

1.2.1 Laboratory Quality Policy

As a quality-minded organization, Bios International is committed to ensuring worldwide customer satisfaction by:

- Posting only conservative product specifications based upon extensive uncertainty analyses;
- Maintaining a laboratory environment and associated services consistent with the guidelines of ISO 17025;
- Providing failure-free, error-free products tested and calibrated in accordance with ISO 17025, our quality documents, and customer requirements, and performed only by personnel fully-trained to comply with the quality requirements, policies, and procedures of our Management System;
- Offering personalized and consistent customer support;
- Meeting our product delivery and service turnaround expectations; and,

- Maintaining a well-trained, motivated work force founded on teamwork and fostered by group activities, an open culture, the free flow of ideas, and advancement opportunity for employees seeking to increase their contributions to the organization.

We understand that our goal of customer satisfaction can only be achieved through the consistency, quality, and efficiency of both our products and our customer service. With this mission in mind, we have established corporate goals and objectives and *communicated and available, and implemented throughout our organization, and understood by the employees*, in order to comply with our quality requirements, provide the resources for continual improvement, and measure our effectiveness.

We use our Management System procedures as a means for meeting and maintaining these goals and objectives. However, meeting and maintaining our organization's goals and objectives goes beyond simply posting these on the wall in the form of our Quality Policy. Rather, our laboratory keeps personnel aware of the relevance and importance of their positions frequently, and through various means.

One way we do this is through one-on-one discussions between Managerial Staff and personnel. These are frequent, highly encouraged, and often impromptu, launched whenever a manager sees an opportunity to relate a specific goal or objective to a situation, task or conversation. Additionally, supervisors are periodically reminded of their own critical roles in imparting Bios International's goals and objectives onto the rest of the staff. Another very effective method for keeping personnel aware, diligent, and motivated is our once weekly company lunch, when all personnel, including the President, sit down to a common meal to discuss company issues and ideals. Company-wide personnel meetings, where staff members are updated as to current goings-on and how these fit into our goals and objectives, are also conducted periodically. Employee reviews is another effective, and formal, means.

Lastly, Management continuously reminds laboratory personnel as to the importance of maintaining integrity of their laboratory functions, such as calibrations. In support of this and at any time, the VP Operations visits the lab personnel at work in the lab to survey the work being done, express his vision and goals for the lab specifically, and the organization as a whole.

1.2.2 Quality Manual

This quality manual defines the scope and structure of the Management System, the related roles and responsibilities of the Managerial Staff, and includes provisions for ensuring compliance with *ISO 17025:2005 and NIST 150:2006*. To accomplish this, this manual includes or references the procedures used within the Management System, and outline the structure of the documentation. Management System documents are organized into three levels: Level 1 documents, which include this quality manual, and provide an overview of the Management System; Level 2 documents, which are the procedures describing the ways in which departments are managed and how these procedures interpret and comply with the organization's policies; and, Level 3 documents, which are lower-level, detailed documents describing how specific tasks are performed, and how specific information is recorded. More information on this topic may be found through QS01-5, Document Control Procedure.

1.3 Document Control

We have detailed procedures for controlling all Management System documents, which include regulations, standards, calibration methods, work instructions, drawings, software, personnel records, specifications, and manuals. All documents relevant to the Management System and/or designated as controlled documents are reviewed and approved by authorized personnel prior to their use, such as by the VP Operations, Quality Manager, Administration Manager, Chief Engineer, Document Control Engineer, and Chief Metrologist.

Once approved, these documents are stored in a central, structured location, ensuring that personnel have access to only active, current-revision documents. This central location is our Document Control system (see Appendix 2 for a listing of documents), located on our computer server. The Document Control system is comprised of numerous files and sub folders, password protected and of "read only" status to prevent deletion, renaming, moving, or editing by unauthorized personnel. Documents stored include current, prior revisions, and obsolete – and all document statuses, names, revision levels, and dates are apparent.

The Document Control system is easily accessed by personnel via “shortcuts” (icons) on their desktop computers. Once within Document Control, personnel may navigate through the files and sub-folders to locate desired documents for viewing, printing, or editing, as authorized.

Document Control arranges all Management System documents (and any controlled documents) into either Documents or Records. Within the Documents and Records umbrellas, procedures and other supporting documents are further grouped by type; for example, Forms and Procedures, Print Literature, Management System Procedures, and Artwork are grouped under the Documents umbrella, while types such as Employee Training Records, Employee Reviews, Customer Satisfaction Reports, and Warranty Statistics are grouped under the Records umbrella.

Handwritten changes to documents are not allowed. Where electronic documents are changed, file properties enable us to identify new or changed text in the document or in approved attachments. The original approving authority reviews and approves changes unless intentionally designated otherwise. We make certain to ensure that authorized personnel have access to relevant background information.

As a prudent safety measure, our Document Control system is routinely backed up by our computer server.

Additionally, a separate file database houses the names and revisions of all Management System documents stored within the Document Control system. This separate database supplements the actual documents stored within Document Control; by use of keyword searches, it provides an easy way for authorized personnel to locate the Document Number, Document Description, Current Revision, Date of All Revisions, and Location of all controlled documents stored within the Document Control system. Authorized personnel edit the records in this database to match those edits made to the actual documents within Document Control. This separate file database is easily accessed by authorized personnel via “shortcuts” (icons) on their desktop computers. The database is located on our computer server, and routinely backed up.

See Document Control, QS01-5, Section 3.1, for delineation of our documentation structure.

Related Procedures:

Document Control, QS01-5

1.4 Contract Review

With quality as our goal, all customer quotes and orders are thoroughly reviewed in accordance with our Management System procedures prior to placement and fulfillment. This review process is called Contract Review, and is handled by the *Customer Service* Staff. The Contract Review process makes sure that all customer requirements are recognized, acceptable, and possible. Ultimately, this ensures that our customers receive what they need, and that Bios International is capable of meeting these requirements, and that both parties are cognizant of the other’s needs and quote or order status. The Contract Review process includes the selection by both the customer and the laboratory of the appropriate calibration methods.

At all times, we strive during the Contract Review process to resolve any incongruities between customer requests and our understanding of, or capability to fulfill, these requests. If for any reason we must deviate from an agreed order due to a change in resources or other circumstances, we quickly inform customers of the deviation, and any changes to orders that have already been processed undergo the same Contract Review as the original orders. Records of our conversations with the customer are stored in the company sales database. These changes are communicated to all relevant personnel by the Administration Staff using the sales database.

All relevant records of this process are kept, including significant changes to quotes or orders, and relevant discussions with our customers regarding their requirements or the results of our work. These are kept with customer paperwork and filed, and/or within our contact database.

Related Procedures:

1.5 Subcontracting of Tests and Calibrations

We do not subcontract calibrations.

1.6 Purchasing Services and Supplies

We adhere to documented procedures governing how we purchase services and supplies and how we evaluate and select suppliers.

We evaluate our suppliers and vendors of consumable materials, supplies and services whenever these have a bearing on our calibration quality. To aid in this, we maintain an approved supplier/vendor list noting the reason each were approved.

Our purchase orders and other purchasing documents contain all information necessary to specify the service or supplies being ordered, and our Purchasing Manager, in conjunction with the VP Operations when necessary for technical verification, reviews all related purchasing documents before approving them for release.

We follow specific procedures regarding the purchase, reception, and storage of supplies or consumable materials that affect the accuracy of our calibrations, and we do not use these items until they have been inspected or verified as conforming to our specifications and requirements. The specifications and requirements defined in our test or calibration methods are determining factors in this inspection/verification process. Any actions we take to ensure compliance are recorded.

Related Procedures:

Purchasing QS01-11

1.7 Service to the Customer

We are committed to complete customer satisfaction, and the *Customer Service* Manager is responsible for ensuring that customer service personnel quickly and accurately decipher customer requests, cooperate with our customers to the fullest extent possible, and understand and adhere to any policies or procedures relating to how we handle customer requests or requirements.

We accomplish this in ways that do not compromise our customers' confidentiality, as we do not share customer information with other parties. The Administration Manager holds formal, periodic customer service meetings and/or trainings, one-on-one talks, or informal group discussions with customer service personnel, ensuring that customer satisfaction and adherence to procedure is the consistent focus of the customer service team. As daily support, a team supervisor works among the personnel, reporting to the Administration Manager throughout the workday as necessary.

Feedback/complaints from customers is a critical tool for not only adequate customer service, but for improved customer service, better products, and better service of our products. Therefore, our customers are encouraged to offer comments regarding any aspect of our organization. We proactively solicit customer feedback by several means, one of which is the sending of postage-paid survey and comment cards in all product shipments (these cards also suggest our website for online feedback, if preferred). Online, we have a customer survey on our home page, and also several free-form comment areas in various "Web-to-Database" forms. Further, our quarterly newsletters have a customer feedback section, and targeted surveys are sometimes sent through a designated email survey tool.

All customer feedback is reviewed personally by the Administration Manager or a designated customer service staff member, and promptly recorded in our customer satisfaction database (see Customer Satisfaction, QS02-13). The Administration Manager is kept apprised of all positive and negative feedback by the customer service staff, and

personally addresses all negative feedback via email, as record of Bios International's feedback response while simultaneously providing a high degree of personal customer support. When possible, customer feedback is added to our contact database so that Bios personnel may view this feedback as necessary. The Administration Manager compares customer satisfaction records to corresponding Goals and Objectives, and presents these in Management Review meetings.

As constant reminder to all Bios International staff regarding the importance of quality customer support, overall laboratory quality, and how these relate to our laboratory's Goals and objectives, a public feedback board hangs on the cafeteria wall. It displays positive customer feedback mined from our feedback solicitations and general company correspondence, and is updated every several weeks.

1.8 Customer Complaints

While not pleasant, we view customer complaints as opportunities to improve our service, our quality, or our procedures. Customer or vendor complaints, whether in the form of solicited feedback surveys, telephone calls, or other methods, are recorded and investigated, and resolved as necessary or as possible, either through personal contact by the Administration Manager, the VP Operations, or a customer service staff member, and/or through internal Corrective Action. Records of the complaint include the results of the investigations and any corrective actions are maintained. This is done as a function of our documented corrective action procedures.

As a matter of course, all customer comments are recorded in *Salesforce database*.

Related Procedures:

Corrective and Preventive Action QS01-03

1.9 Control of Nonconforming Tests and Calibrations

We have documented procedures to maintain the validity of our calibrations. Although we always do our best to perform only quality calibrations, in the event of a nonconforming calibration we refer to the Nonconforming Product procedure (QS01-09) to tell us how to handle this situation.

This procedure clearly defines the authority, responsibility, and management of nonconforming work. During this process, we quickly evaluate the significance of the calibration or test nonconformance, and as necessary halt further work, withhold invalid results, recall the calibration work, and/or notify the customer. In the event that work was indeed halted and/or results withheld, the responsibility and authority for the resumption of work and restating of results is clearly defined within the procedure.

If, during the course of this process and our investigation, we come to believe that the nonconformance might happen again, or may influence the accuracy of related tests or calibrations, we initiate timely corrective action.

Related Procedures:

Nonconforming Product QS01-09

1.10 Corrective Action

When we discover problems with our calibrations or deviations from our established Management System procedures, we remedy the situation through a controlled corrective action process. The corrective action procedures designate the individual with authority over this process, and define the corrective action implementation. In short, this process addresses issues identified during internal or external audits, Management Review, customer feedback, staff observations, or internal quality control measures.

When a problem is discovered, it is immediately investigated by a manager or a supervisor in order to determine its severity, root cause, and if formal corrective action is necessary. If an authority figure, such as the VP Operations, decides to initiate a corrective action, it is directed specifically at the problem's root cause to reduce the chances of a

recurrence. The depth of the corrective action is relative to the severity of the problem and the risks it poses to the laboratory's quality.

All aspects of the corrective action process are documented and monitored to ensure that the appropriate corrective action not only takes place, but is effective.

When a nonconformance in our Management System casts doubt upon our ISO 17025 compliance, we promptly undergo an internal audit of the area in question.

Related Procedures:

Corrective and Preventive Action QS01-03

1.11 Preventive Action

While corrective action is a reaction to a discovered problem, preventive action is a critical facet of monitoring our Management System in order to maintain the quality of our calibrations and overall operations. As we monitor our organization and glean useful information, we use this information to identify needed improvements or potential sources of nonconformance. This often occurs within Management Review meetings, but may occur at any time in between. When appropriate, proactive plans, or preventive actions, are developed to initiate action to prevent the cause of potential identified problems. Management both implements and monitors these action plans to make sure they take place, are consistent, and effective. During management reviews *preventive actions* and opportunities for improvement are identified and acted upon.

Related Procedures:

Corrective and Preventive Action QS01-03

1.12 Control of Records

We have documented procedures in order to identify, collect, index, file, store, maintain and control access to our quality records. Our quality records include technical records, internal audit records, management review records, corrective and preventive action records and any other supporting records. Our technical records include original observations, derived data and sufficient information to establish an audit trail. We also keep calibration records, staff records and calibration certificates.

All quality records are legible, retrievable and prevented from damage, loss or deterioration. We keep these records secure and confidential and, whenever possible, in electronic form as ultimate protection against tampering and loss. All electronic media are systematically backed up by our computer systems (main server).

All records are retained for specific periods of time as noted in the the QS02-07, Records Log. The Records Log is comprised of 15 document "buckets" (such as Obsolete Documents, Training Records, Calibration Records, Manufacturing records, and Audit Reports), and in addition to detailing the minimum time we must hold these documents and records, it also explains how each is filed (such as electronically, or paper-copy in a binder); where each is filed (such as our computer server); the approved method of disposal (such as shredding); and finally, security access information (who among the Bios international staff are authorized to view or handle these documents).

Calibration records are made when calibrations are conducted, and then linked to each specific calibration, at the same time identifying the individual who performed the tests and interpreted the results. Our calibration records allow us to identify factors affecting the calibration's uncertainty, and to repeat the calibration under conditions similar to the original instance.

When errors occur in records, corrections may be made only by crossing out the errors and writing in the correct values. Erasing, whiting-out, or other means that render the original error illegible are not allowed. All corrections are initialed by persons with express access to those records. Wherever electronically stored records are changed, similar measures are taken to ensure the original data is preserved.

Related Procedures:

Document Control QS01-05

1.13 Internal Audits

The Quality Manager (the VP Operations) schedules and oversees periodic auditing of the Management System based on the internal auditing procedure. These audits ensure that we comply with our own procedures, Management System, and ISO 17025. The audit program includes all elements of our Management System and calibration operations.

These audits are planned and organized as required by the audit schedule and when requested by management. We ensure all auditors are trained and qualified and are independent of responsibility for the area in audited.

Whenever our audits question the effectiveness of our operations or the accuracy of our calibrations, we ensure the audit findings are processed in accordance with our corrective action procedures. Our records include the area audited, the findings, and corrective action taken. If findings indicate that test results may have been affected, we notify the affected customer in writing. Follow up audits are used to verify and record the implementation and effectiveness of corrective action.

Related Procedures:

Internal Auditing QS01-01

1.14 Management Review

Management review meetings are scheduled to occur at least once a year. Additional meetings may occur when senior management feels it would be beneficial to the organization. The meeting will consist of all top management members including the Technical Manager. The meeting will be chaired by the Management Representative. The and At this time, we review the overall Management System and our calibration activities (considering the quality objectives and goals of our company), as well as the suitability of our policies and procedures, reports from other managers and supervisors, internal audit results, corrective actions, preventive actions and assessments by external bodies, and any necessary changes or improvements. We also consider the results of inter-laboratory comparisons, changes in work volume or type, feedback and complaints from customers, and other relevant factors that arise.

Thorough and complete records of our management review meetings are kept, including any action items, the assigned personnel, and time frames. Future management review meetings discuss whether personnel have completed their action items on a timely basis.

Related Procedures:

Management Review QS01-08

1.15 Improvement

As a quality-committed laboratory, we continually seek to improve our Management System, and this begins with our Management Review meetings. With top management attending these meetings, brainstorming courses of action, following through with action items, and assessing results from previous meetings, the laboratory's improvement relies on productive Management Review.

There are a number of ways improvement is achieved through the Management Review process. Here, internal audits are discussed, and any deficiencies exposed, triggering corrective and preventive actions. Customer feedback is cited, both negative and positive: negative comments may be acted upon to improve our handling of situations where we fail or fall short, while specific positive feedback emphasizes those practices which improve our organization and enhance our customer service.

From a statistical standpoint, analysis of trends helps the President analyze production's deviation percentage from our standards, and the deviation from our standards to our laboratory masters. Other quality reports, such our warranty records and customer "promise dates" tell us where we need to better train our employees, address vendor issues, update

our quality procedures, hire additional employees, or increase or decrease our delivery and service time estimates to customers.

Our quality Goals and Objectives are another critical tool for continual improvement, and as needed and within reason, they are subjectively “tightened” or “relaxed.” Specifically, we make more challenging any goal or objective that is too easily and consistently reached in a given area, forcing us to enhance some aspect of our quality, our output, or our customer service. Conversely, we lower any goal or objective that is too consistently difficult, and therefore probably unreasonable, given our current means. Relaxing a goal or objective allows our organization to ultimately achieve it. Once achieved, we can analyze what it was that enabled us to achieve our goal or objective, versus why we were not able to do so previously. This insight enables the laboratory to revise, improve, or add to any personnel issues, procedures, or policies until we can eventually raise this goal or objective in the near future.

2.0 Technical requirements

2.1 General

We acknowledge that many factors contribute to the total uncertainty of measurement in our calibrations. Therefore, we consider all factors relevant to our calibration accuracy, methods, and procedures. As such, training, qualification, methods, and equipment are appropriate to the factors contributing to uncertainty, such as human error, accommodation and environmental conditions, calibration methods, method validation, equipment, traceability, handling and other factors.

2.2 Personnel

Management allows only competent and qualified personnel to perform activities that directly or indirectly influence the quality and/or accuracy of calibration tests. Such personnel include those who operate calibration equipment, perform calibrations, evaluate results, sign certificates of calibration or perform supporting tasks, such as customer service and order processing. We directly employ all personnel. When qualifying personnel for such tasks, we always consider education, training, experience, and demonstrated skills as required for the task. Where personnel performing tasks are not yet trained or qualified, we require that a trained personnel member supervises these tasks, and that the work product is inspected, as well.

We devise goals for the education, training, and skills of our personnel according to our procedures. These procedures ensure that training needs are identified and subsequently provided. Training is always relevant to both present and anticipated; near-future tasks the employees are and/or will be performing.

Only specific personnel deemed competent to perform tasks critical to the calibration process, such as calibration, issuing certificates, or interpreting data, are allowed to do so. We maintain detailed job descriptions for management, technical, and support personnel whose work relates to, or supports, calibrations. These job descriptions are readily available through our Records portion of our Document Control database, and reference an employee’s responsibilities involving the performance of calibrations, planning of calibrations, reporting of results, and the determining of calibration methods, as well as indicate the expertise and experience required, qualifications, and training programs required and any managerial duties. Additionally, we keep records regarding the authorization of these employees to become involved in calibrations; this information is also readily available, and includes the specific dates that authorizations were given.

Related Procedures:

Training QS01-15

2.3 Accommodation and Environmental Conditions

Stable laboratory operating conditions are necessary for proper metrology. As such, our calibration laboratory is housed in an enclosed space to guard against cross-contamination from neighboring areas, with laboratory ingress and egress doors closed at all times. Our laboratory environment is kept clean and free of clutter, with all laboratory personnel responsible for “good housekeeping.” Housekeeping procedures are defined verbally when necessary.

To maintain a stable laboratory environment, energy sources, lighting, and environmental conditions are monitored and controlled as necessary in order to preserve the accuracy of our results and the quality of our measurements. Dust is not a factor in our laboratory, because, 1) the air we use is pressurized clean air not open to ambient; and 2) we also use bottled nitrogen; and, 3) the laboratory doors are always kept closed, and neighboring areas are of very low activity and do not involve particulate-producing processes (such as machining). Our laboratory's temperature and humidity are controlled by a precision HVAC system, designed specifically for this purpose. Vibration is not a factor in our environment, and in general our laboratory is a quiet, clean, liquid- and hazard-free area, with virtually all of our functions attributed solely to gas flow measurement of Bios calibration systems.

On a weekly basis, and before calibrations, a designated laboratory staff member downloads data from our temperature and humidity recorder, analyzes the data, and looks for fluctuations or other anomalies. Once downloaded, this data is backed-up automatically by our computer server's weekly back-up schedule.

Wherever tests are conducted necessarily outside of our controlled laboratory, as necessary we do whatever we can at that time, at that site, to maintain good environmental conditions. The requirements for environmental conditions, whether at our site or off-site, will be documented as necessary at that time.

In the unlikely event that the laboratory's environmental conditions are no longer conducive to accurate calibrations or tests, we will immediately halt all calibration activities until the situation is rectified. A call to halt will come from the President, the VP Operations, the Chief Engineer, or the designated laboratory supervisor, and all laboratory personnel will be asked to exit the laboratory as necessary. The President, the VP Operations, or the Chief Engineer will assess the situation, confer with the others as necessary, and determine for how long calibration operations must remain suspended, and the situation explained to the laboratory supervisor, who is responsible for making sure that all relevant personnel are aware of the halt order and that calibrations and/or tests do not resume until further notice. A corrective action will be raised to address the issue. Instrument calibration will not be re-started until approved by the Chief Metrologist.

Related Procedures:

Environmental Control QS01-06

2.4 Test and Calibration Methods and Method Validation

2.4.1 General

Bios has identified the methods and procedures for calibrations conducted within our scope, including applicable methods for handling, transport, storage and preparation of items to be calibrated, are followed. When necessary, we include an estimate of uncertainty relating to our calibrations. We also specify statistical techniques for analyzing our calibration data.

We keep instructions for using and operating our calibration equipment and for handling and preparing items for calibration wherever the absence of these procedures might jeopardize the results of the calibration. All instructions, standards, manuals or other critical calibration documentation are kept up-to-date, and available in accordance with our document control procedures. We follow these procedures in all cases, except where a deviation has been documented, technically justified, and authorized, both internally and by the customer.

2.4.2 Selection of Methods

In all instances, we use only the applicable international, federal, or industry method of calibration, using the latest revision of any relevant international or federal specifications available. As necessary, we support the standards with additional procedures so that the specification is applied effectively. Prior to introducing standardized methods for the first time, we conduct tests in order to confirm that we can properly follow the requirements of the standard. If the standardized method changes, we repeat this process.

If our customer specifies a calibration method that is inappropriate or out-of-date, we work with our customer to effectively resolve the issue prior to commencing our calibration work.

If our customer does not specify the calibration method to be used, we let our customer know of the method chosen by our laboratory, and this is always the applicable international, federal or industry method. Or, as necessary, we use methods we have developed ourselves. When using methods internal to our laboratory, these methods are always suitable for the intended use and validated beforehand.

Related Procedures:

Lab Proficiency QS01-07

2.4.3 In-house Methods

The definition and introduction of calibration methods developed in-house are only assigned to qualified personnel and conducted according to documented project plans. All personnel are furnished with adequate resources to develop these methods. We update the developmental plans wherever needed, while effectively communicating this process to all pertinent personnel.

Related Procedures:

Lab Proficiency QS01-07

2.4.4 Nonstandard Methods

When we use nonstandard methods that are not included in international, federal or industry methods, we obtain client agreements and include a clear specification of the client's requirements and the purpose of the calibration.

Prior to introduction of the method, we define the method and documented procedures which include, as applicable:

- Identification of the method
- Scope
- Description of the calibration item
- Parameters, quantities or ranges to be determined
- A description of the equipment and its performance requirements
- A description of required reference standards or materials
- A description of environmental conditions and any stabilization period needed
- A description of the procedure, including:
 - Any identification marks, handling transportation, preparation or storage requirements
 - Any checks to be made prior to commencing work
 - Any equipment checks or calibrations to be made prior to use
 - The means of recording observations and results
 - Any safety measures
- Criteria for approval or rejection
- Data to be recorded and means of data analysis and reporting
- The uncertainty or the means for estimating uncertainty

Related Procedures:

Lab Proficiency QS01-07

2.4.5 Validation of Methods

All nonstandard methods, methods designed in-house, or when standard methods are used differently than originally intended, are validated prior to our use. The validation process is as thorough as it needs to be, considering the nature of the test and the requirements of the customer. We make sure to record the measures taken to validate the method, the results obtained, and the determination as to whether or not the method is appropriate for the measurement.

As an accredited laboratory, we always make sure that the technical capabilities, including range and accuracy, obtainable from the validated method are relevant to the client's needs. Parameters to consider may include:

- Uncertainty
- Detection limit
- Selectivity
- Linearity
- Repeatability
- Reproducibility

Related Procedures:

Lab Proficiency QS01-07

2.4.6 Estimation of Uncertainty of Measurement

Our procedures describe the manner in which we identify all known uncertainty sources in our calibrations and make statistically valid estimations of uncertainty. Subsequently, we present the uncertainty in such a way that our overall measurement uncertainty is not only accurate, it is clear.

Related Procedures:

Lab Proficiency QS01-07

2.4.7 Control of Data

Systematic checks and verifications are performed on any calculations or data transfers that affect calibration accuracy. If we use computers or other automated equipment for acquiring, processing, recording, reporting, storing, or retrieving data, these are checked and verified as necessary. Additionally, any software developed in-house is documented and validated prior to use.

We have procedures for protecting the collection of data, its storage, transmission, and processing. As usual, our computers and other automated systems are maintained and backed-up regularly to preserve data accuracy.

Related Procedures:

Lab Proficiency QS01-07

2.5 Equipment

To maintain our calibration efficiency and to prevent the use of inappropriate or inadequate equipment in our calibrations, we keep all necessary measuring and test equipment in specific facility locations, accessed and operated only by calibration personnel.

At all times, the equipment we use exhibits the accuracy needed in order to meet our requirements for compliance, and this includes calibrating the equipment regularly in accordance with an established calibration system. This system takes into account all relevant characteristics of the equipment so that it is calibrated properly prior to placing it in service. If ever we need to use non-Bios International equipment, we take steps at that time to make sure that any relevant requirements of ISO 17025 are met. Our calibration personnel always have current instructions and/or procedures governing the use and maintenance of our equipment, including any OEM manuals for non-Bios equipment.

All equipment needing periodic calibrations are uniquely identified, indicating their calibration statuses, dates last calibrated, and due dates. As such, each piece of equipment is supported by records that:

- Identify the equipment and its location
- List the manufacturer’s name, model, serial number or other unique identification
- Check that the equipment complies with the specification
- Include the manufacturer’s instructions and/or reference their location
- Include the date, results and copies of calibration certificates
- Note any adjustments made during calibration
- Note acceptance criteria
- Reference the due date for the next calibration
- Identify the maintenance plan (as appropriate), and detail the maintenance carried out to-date

- Describe any damage, malfunction, modification or repair

Our procedures include the safe handling, transport, storage, use and planned maintenance of measuring equipment wherever necessary to ensure proper functioning and accuracy. These procedures also include safeguards to prevent any unauthorized adjustments that may invalidate the results.

Any equipment that has been overloaded, mishandled, or is suspect for any reason, is promptly removed from service and rendered unavailable for use, or clearly identified as defective, until it has been repaired and recalibrated and restored to specification and/or full performance. The defect is examined to determine what ramifications, if any, this defect may have had on previous calibrations, and whether the defect constitutes a nonconformance that must be summarily addressed in accordance with our nonconformance procedures.

When equipment is outside our direct control for any length of time, a designated technician examines the equipment for damage or calibration issues upon its return to our facility. If no issues are identified it is placed back in service. When anomalies are identified, the instrument is returned for repair/calibration. If spot-checks are required between formal calibrations, a technician performs these checks using a documented procedure. If our equipment calibrations give rise to a set of correction factors, we implement these factors according to appropriate calibration procedures.

Related Procedures:

Calibration QS01-02

2.6 Measurement Traceability

2.6.1 All equipment used for calibrations or used in a supporting role that has a significant effect on the accuracy or validity of the calibration is calibrated prior to being placed in service, in a way that complies with established calibration systems and procedures.

2.6.2 Calibration Requirements

Our calibration system is designed so that all calibrations and tests we perform are traceable to Standard International (SI) units.

We accomplish this by establishing and documenting an unbroken chain of calibrations or comparisons linking our measurements to the SI units. Links may be directly to a primary standard based on fundamental physical constants, or based on secondary standards by another national metrology organization. Where external calibration services are used, such as those for the instruments and gauges we use as measurement tools (for instance, a depth micrometer) we verify that this outside organization can prove traceability, and demonstrate competence and capability, and that we receive valid calibration certificates, including the measurement results and uncertainty, and/or that they indicate compliance with identified metrological specification.

To enhance our credibility, and in situations where it is impossible to provide traceability to SI units, we assure confidence in our measurements by establishing traceability, as necessary and applicable, by:

- Conducting inter-laboratory comparisons and testing, both informal and formal, with other ISO 17025 laboratories, whether commercial or national, both in the United States and abroad;
- The use of certified reference materials to give a reliable characterization of a material;
- The use of specified methods or consensus standards that are clearly described and agreed by all parties concerned

Our policy is to make these records – including our inter-laboratory comparisons with national labs including NIST, NMIJ, and LNE – available to any customer who wishes to review them. We have mechanisms in place, such as online request forms and automated email response templates, to make it easy for our customers to request such documentation and for our customer service personnel to provide them.

Related Procedures:

Calibration QS01-02

2.6.3 Reference Standards and Reference Materials

Wherever we use reference standards or materials, we maintain a documented system for their calibration and use so that the reference standards are calibrated in a traceable manner, as described in section 2.6. We use reference standards for calibration only, unless we prove that their performance as reference standards is not invalidated by other use. Reference standards are calibrated before and after any adjustments.

Whenever possible, reference materials are traceable to the SI units or to certified reference materials, and any internal reference materials are checked to the full extent of our technical capability. As necessary, we conduct intermediate checks (spot-checks) to maintain confidence in their calibration status and accuracy, according to our documented procedures and/or schedules. Our procedures define any requirements for safe handling, transport, storage, and use of these reference standards, as well as any requirements for the reference standard to be transferred to a working standard.

Related Procedures:

Calibration QS01-02

2.7 Sampling

We do not perform sampling applications in our laboratory.

2.8 Handling of Calibration Items

We have documented procedures governing the transportation, receipt, handling, protection, storage, attention and disposal of the calibration items we handle. These procedures include any provisions necessary to protect the calibrated item from damage and/or deterioration and ensuring both our interests and our customer's interests are met.

Our procedures include provisions for identifying calibration items, and identification is retained throughout the item's "life" in our facility, preventing items from being either confused physically or within our records. With this system, we can accommodate groups of goods and transfers of goods within our organization and to outside organizations.

When we receive calibration items, any abnormalities or departures from standard conditions are recorded. If an item is unsuitable for calibration for any reason, we let the customer know prior to proceeding. Our customer service personnel keep details of the customer correspondence in our support database for future reference.

Our operations are designed to prevent our calibration items from being lost, damaged, or deteriorating while under our control. If needed, specific handling instructions follow a calibration item. If calibration items need to be stored or handled under specific or unique conditions, we provide, monitor and record the conditions.

Related Procedures:

Shipping and Receiving QS01-14

Production QS01-10

2.9 Ensuring the Quality of Test and Calibration Results

We maintain documented procedures for monitoring the validity of tests and calibrations conducted under our responsibility, recording quality control data in such a way that trends can be detected and statistical techniques applied to the reviewing process for better results. Our quality control monitoring is planned and reviewed appropriately, and may include the following:

- The use of certified reference materials
- The use of internal quality control using secondary reference materials
- Inter-laboratory comparison
- Proficiency testing programs
- Replication of testing or calibrations

- Retesting or recalibration of retained items
- Correlation of results for different characteristics

When calibration issues are identified a corrective action is raised to address the issue.

Inter-laboratory comparisons, both formal and informal, were performed over the past several years. The results are detailed within two technical papers, which were written for presentation at major symposia. These papers are stored on our main computer server, and are accessible by appropriate Bios personnel as needed. The two technical papers containing our inter-laboratory results are:

1. MSC 2004 (34th Measurement Science Conference; Anaheim, CA 2004): Includes results with NIST (April and October 2003); NMIJ (May 2003); National Lab 1 (Sandia); National Lab 2 (NMI); Commercial Lab 1 (Celerity); and Commercial Lab 2 (Flow Dynamics).
2. ISFFM 2006 (6th International Fluid Flow Measurement Symposium; Queretaro, Mexico May 2006): Includes results with LNE/BNM (October 2004 and March 2005).

Related Procedures:

Lab Proficiency QS01-07

DryCal Flow Calibration Quality Control Plan QS01-16

2.10 Reporting Calibration Results

We report the results of each calibration or series of calibrations accurately, clearly, and objectively, within a calibration certificate, as well as within supporting documentation as necessary or requested. These include all information requested by the customer as well as any information necessary for the interpretation of the calibration results, and any information required by the method or standard used. The format of our calibration certificates and any supporting documentation accommodates the type of calibration performed. If we perform calibrations for internal clients, or when the customer requests it in writing, we may report the results in a simplified manner. Whenever we transmit calibration results by telephone, fax, or email, we do this in compliance with the requirements of this manual and ISO 17025.

Any information required under our normal reporting procedures is retained at our facility, and each calibration certificate includes at least the following information:

- A title for the calibration certificate
- A "Page 1 of 5" format or equivalent
- Name and address of the customer
- Our name, address, and location
- A unique identification of the calibration certificate, such as the serial number of the calibration item
- The description of, or the condition of, and/or a clear identification of the calibration item
- The date that the calibration was performed
- The date of the receipt of the calibration item where this is critical to the validity or application of the results
- Identification of the method used
- The calibration results with the units of measurement, where appropriate
- Where relevant, a statement to the effect that the results relate only to the items calibrated
- The general conditions under which the calibrations were performed which may have an influence on the results
- The uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- Evidence that the measurements are traceable
- The name, function and signature or equivalent identification of any person or persons authorizing the calibration certificate

Generally, the calibration certificate only relates to quantities and results of functional tests. However, if a statement of compliance with a specification is made, the certificate identifies which causes of the specification are met, and identifies any exclusions.

If we merely state compliance with a specification without providing specific measurement results and uncertainties, we record and retain those results for possible future reference. When determining compliance to a standard, we consider the uncertainty of measurement.

When an instrument for calibration has been adjusted or repaired, we include the calibration results before and after the adjustment or repair, whenever these are available. Our calibration certificates and calibration labels do not include recommendation on the calibration interval unless this has been agreed with the customer (please note that this requirement may be superseded by legal regulations). Whenever we include opinions and interpretations, we explain the basis for our opinions and interpretations, clearly marking opinions and interpretations in any reports or certificates. When applicable to the instrument (cell), the calibration label will be applied to an area that would indicate that the instrument has been compromised.

We control any material amendments made to a calibration certificate once it has been issued, so that amendments meet the requirements of this manual and ISO 17025, and are made only in the form of further documents or data transfer that include the statement "Supplement to calibration certificate number XXXX" or "Supplement to serial number XXXX" or equivalent. If it is ever necessary to issue a completely new calibration certificate, it is uniquely identified and references the original. The calibration certificate identifies the calibration location.

Related Procedures:

Test Rata Reporting QS01-12

Appendix 1 Scope

The Bios International laboratory Management System applies to the following calibrations:

MECHANICAL

NVLAP Code: 20/M05

Flow Rate

Range in sccm	Best Uncertainty (±)
1.0 to 2.5	0.163%
2.5 to 5.0	0.127%
5.0 to 50,000	0.071%

TIME AND FREQUENCY

NVLAP Code: 20/F01

Frequency Dissemination

Range	Best Uncertainty (±)
0.1 Hz to 10 MHz	0.000025% Frequency Period 200 ns to 10 sec

THERMODYNAMIC

NVLAP Code: 20/T05

Pressure

Range	Best Uncertainty (±)
0 kPa to 1 kPa	0.15 kPa
87 kPa to 173 kPa	3.47 Pa

NVLAP Code: 20/T07

Resistance Thermometry

Range in °C	Best Uncertainty (±)
-20 to -5	0.05°C
-5 to 70	0.03°C
70 to 130	0.03°C

Appendix 2 Procedures and Work Instructions

Appendix 2 is a Master List expanded file directory: a snapshot of Management System documents (procedures, work instructions, quality manual, employee training, and other related documents) housed within a system of computer files and sub folders called "Document Control."

Document Control is stored within, and accessed through, the Bios computer server. Bios employees with access to either view or edit the documents referenced by Appendix 2 may do so through Document Control icons on their computer desktop.

The controlling mechanism for all Bios documents within our Document Control system is detailed in Section 1.3.

Appendix 3

Laboratory description

Appendix 4

Laboratory images and dimensions

Annex A

Referencing NVLAP Accreditation

This is fully addressed in the Bios International procedure of the same name, QS01-17.

Annex B

Implementation of Traceability Policy in Accredited Laboratories

As an ISO 17025 accredited laboratory, the results of Bios International's accredited calibrations, and the results of all calibrations required to support accredited tests, are traceable to the SI (International System of Units) through standards maintained by NIST.

Please see the attached three documents regarding Bios International's uncertainties:

1. ML-800 Uncertainty Statement-10 (1-4-06)
2. ML-800 Uncertainty Statement-24 (1-4-06)
3. ML-800 Uncertainty Statement-44 (1-4-06)

Further, the source spreadsheet is in Excel format, entitled ML-800 Uncertainty Analysis (1-4-06), and is available on our main computer server, under a system of folders with limited access: Users - Collaborative - Metrology Studies - Lab Proficiency (final placement folder for this Excel document).

Approved Signatories

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