Boise Calibration Service, Inc.

Quality Systems Manual

1. Introduction

This Quality Manual (BCL-001) describes the Quality Management System (QMS) in place at Boise Calibration Service. The intent of this Quality Manual is to demonstrate compliance of Boise Calibration Service to ISO/IEC 17025:2005 standards.

The policies, procedures and other related documents referenced herein comprise the complete QMS in place at Boise Calibration. This quality manual has precedence over all other documents described herein in the event conflict between documents is encountered.

The format of this manual has been written to run parallel ISO/IEC 17025:2017 for ease of cross-reference and identification of specific ISO/IEC 17025:2017 requirements.

2. Scope and Document References

This document specifies a quality system to demonstrate our capability to deliver calibration and repair services, based primarily on ISO/IEC 17025: 2017. It also conforms to the requirements of ISO 9001: 2015, ANSI/NCSL Z540-1: 1994, ISO 10012-1: 2003, and Mil-Std-45662A (obsolete). In addition, it uses many terms from ISO 9000: 2015. 1.3 This document is primarily aimed at achieving customer satisfaction by providing customer oriented solutions at all stages of our operations by adherence to our corporate policies and procedures.

Document requiring periodic changes to reflect new technology, changing client expectations and improvements to the quality system. For documents referenced in this manual the most recent edition applies.
ANSI/NCSL Z540-1: General requirements for calibration laboratories and measuring and test equipment, hereinafter referred to as ANSI Z540-1. (DCN 10039)
JCGM 200: 2012 (VIM) International Vocabulary of Basic and General Terms in Metrology. (DCN 10089)
NCSL GLOSSARY: NCSL Glossary of Metrology Related Terms. (DCN 10044)
A2LA: R101 General Requirements for Accreditation of ISO/IEC Laboratories. (DCN 10036)
A2LA: P102 Policy on Measurement Traceability. (DCN 10058)
A2LA: R103 General Requirements: Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories. (DCN 10059)
A2LA: R104 General Requirements for the Accreditation of Site Testing and Site Calibration Laboratories. (DCN 10033)
A2LA: P101 A2LA Advertising Policy. (DCN 10060)
A2LA: R205 Specific Requirements for Calibration Program Requirements (DCN 10061)
A2LA: P104 Policy for Claims of Measurement Uncertainties for Onsite Calibration on Scopes of Accreditation (DCN 10022)
A2LA: R103A Annex: Proficiency Testing for ISO/IEC 17025 Laboratories (DCN 10059)
A2LA: R218 Applications for Calibration Scopes of Accreditation. (DCN 10065)
EA-4/02 Expression of the Uncertainty of Measurement in Calibration (DCN 10025)
NIST 1994: Tech Note 1297: Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results (DCN 10024)
P14 ILAC Policy for Uncertainty in Calibration

2.2 Internal References

Boise Calibration Services Referenced documents are identified in italics throughout this manual.

3. Definitions

Equipment - Equipment items used for, or under, test and/or calibration activities

Calibration Reference Standards - Standards or equipment owned by Boise Calibration; some calibrated by NIST or ISO/IEC 17025:2005 accredited laboratories

Documents - Documents (internal and external) may consist of drawings, procedures and/or instructions, specifications, tables and charts, policy statements, forms, notices and software. Documents may exist in various media, whether in hard copy or electronic form, and may be digital, analog, photographic or written.

3.1 Understanding internal documents

Control Document (CD): Hard copy receipt that lists all equipment picked up or delivered to the Company by or for a client. It indicates whether accessories were included and that we have temporary possession of ME. The white original is given to the client. The yellow copy is retained by the Company and used to receive the items and generate the **Work Order**.

Work Order: The main system control document used in the process of routing and controlling work and retaining work information. The Work Order is created in two sections that are explained below. The technician is responsible for ensuring the accuracy of the Make, Model, and S/N entries. Technicians must review every service code on the Work Order prior to commencing work to ensure they perform all of the services requested by the client. Additional client information is listed in the event the technician or Technical Manager needs to contact the client.

Top Portion: Includes Customer information. This portion is returned to the customer with the ME.
Name and address of company sending item in for service.
Job number assigned to this job becomes Calibration Certificate number.
Date item received from client.
Accessories (marked if included): In addition to noting them in the computer all accessories will be attached to unit if at all possible.
Probes: Leads, Probes, or other extensions.
Cover: A partial enclosure made for the unit.
Cord: Power Cord.
Case: A complete enclosure made for the unit.
Pouch: An attached bag or case that holds accessories.
Manual: Service Manual or Operating Manual.
Description of the Instrument:
Make: Manufacturer of item.
Model: Manufacturer's model number of item.
Serial Number. (S/N) Unique alphanumeric identifier for item, preferably assigned by the manufacturer.
Prop: Abbreviation for Property Number. Client defined identification number for item.
Brief description of item.
Dept: Client defined department for tracking purposes.
PO#: Purchase order number for work authorized.
Ship Via: What method to get the unit back to the customer
Insure for: If customer has requested shipping insurance the value is listed here.
Rcvd Via: How the unit got from the customer to us.
Rcvd By: The person at the company who logged it into the system.

Bottom portion: Includes secondary section for Job Number, Make, Model, Serial, Prop, and Desc. Additionally it includes:

Rush: Marked if the customer has requested rush services and has agreed to pay for them.
Warranty: Marked if the customer is returning the unit with a complaint.
Repair: UUT may require repair, may be inoperable or the client has notified us they think something is wrong with the equipment.

OnSite: Marked if the work is to be done at the Customer's location.
Need by Date: Requested return date
Tolerance: The tolerance for the tool, or manufacturers specs if multiple tolerances.
Reported Instrument Problem: What the customer has told us about the instrument.
Customer Notes to Technician: Notes from the customer file in the database that apply to every item serviced for that customer.
Reported instrument problems/instructions: Specific problems/instructions as per the customer.
Cal Interval: The time between calibrations the customer has selected.
Suggested Standards: Standards that have been used to calibrate that make/model before.

Received Conditions - Received Tolerance: What the technician observed as he or she began taking measurements.
In Tolerance: Measurements were within the expected range.
Out of Tolerance: Measurements were outside the expected range. Technician is to note direction and amplitude of out of tolerance condition for level 1 calibrations.
Functional: Unit seems to be working correctly; no measurements are available for this type of unit.
Limited: Unit has previously had a problem that does not interfere with using other aspects of the unit.
Other: Technician must specify situation.
Damaged: Unit is damaged, no data can be taken.
Malfunction: Unit is working incorrectly.
Non-Functional: Unit is not working at all.

Returned Conditions: This is how the technician has left the instrument after calibration.
In Tolerance: Measurements were within the expected range.
Out of Tolerance: Measurements were outside the expected range. Technician is to direction and amplitude of out of tolerance condition.
Functional: Unit seems to be working correctly; no measurements are available for this type of unit.
Limited: Unit has a problem that does not interfere with using other aspects of unit. The specifics about the limitation are to be listed, and noted on the sticker.
Other: Technician must specify situation.
Damaged: Unit is damaged, no data can be taken. It has been determined to be not repairable, or the customer has requested no repairs be attempted.
Malfunction: Unit is working incorrectly. It has been determined to be not repairable, or the customer has requested no repairs be attempted.
Non-Functional: Unit is not working at all. All attempts at troubleshooting have failed.

Action Taken: What was done to the unit.
Calibrated: Measurements from this unit was compared to our standard, data may or may not have been taken at the time.
Adjusted: Measurements were adjusted to measure more accurately.
Charted: Measurements were recorded in a chart format.
Op Checked: Item has been tested for functionality.
Repaired: Unit has been repaired. A description of the repair will be listed.
Repaired/Adjusted: Unit has been repaired, adjusted, or both. Details will be listed.
Return As Is (RAI): No changes have been made to the unit.
Calibrated w/Parts: Parts have been replaced that do not affect the calibration.

Corresponding Information:
Cal Date: Date the calibration occurred.
Temp °C: Temperature at the time of calibration, recorded in centigrade.
%RH: Relative Humidity at the time of calibration.
Tech#: Employee number of the technician who performed the calibration.
Standards Used: Standard numbers of the company equipment used to perform the calibration.
Comments: Any information the technician needs the customer to know about the equipment. Includes notes on all out of tolerance conditions, adjustments, parts used, and repairs.

Certificate of Calibration (CofC): The main certification and hard copy of the work performed, data collected and traceability control document. It is generated from the work order number after final inspection. It is digitally signed after final inspection.

4 General Requirements

4.1 Impartiality

Laboratory Activities shall be undertaken with concern to impartially and structured and managed to safeguard impartiality.

4.1.2 Laboratory Management shall be committed to impartiality. The Quality Manager is to ensure that the management system related to quality is implemented and followed always. The Management Team is to ensure that all personnel are free from any undue internal and external pressures and influences that may adversely affect the quality of the calibrations. All employees are to avoid involvement in any activities that would diminish confidence in the competence, impartiality, judgment, or operational integrity of themselves or BCS. Reasonable production discussions are acceptable as long as the quality of work is first.

The following are not acceptable under any circumstances:

Harassment or Intimidation of any employee for any reason;

Offering financial remuneration on a piece basis or individual calibration;

Performing work on equipment that is provided to BCS Calibrations for service for a competitor for personal gain of one employee or group of employees rather than BCS Calibrations as a business.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

Company personnel are restricted from accepting any gift or gratuity beyond an occasional, reasonably priced meal during business, accepted only to facilitate business discussions. This meal should never rise to a price that may put the employee in a debt of gratitude to the client. Token gifts valued at less than $25.00 e.g.; a coffee mug or hat bearing the logo and/or name of the giver's business or product.

While we do not practice direct sales, we will act as our customer's agent in procuring an item, but will never stock an item as a replacement for a non-repairable item. We do not want our staff to be tempted to declare something as non-repairable strictly to facilitate a sale of replacement equipment and / or to increase profits based off of sales of replacement equipment rather than performing cost effective repairs.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from relationships of its personnel.

Identified Risk:

Calibration services;

Key calibration technicians – BCS goal is cross training most technicians so that no one parameters has only one technician that can perform the calibration.

Key calibration vendor services

Key calibration standards

Interlab Relations;

Interactions between labs will be performed in such a way that impartiality is not questioned.

When another lab has BCS calibrate their ME, it will be processed and calibrated to the same rules, procedure, calibration, and quality as all of the rest of BCS customers.

Vendors that BCS sends ME for calibrations they will not make undue requests for favor, whether it is customer or BCS ME.

Working with other labs, such as PT interlabs or Round Robins, will be done in such a way that does not question impartiality.

Internal Relationships;

However, such relationships do not necessarily present a laboratory with a risk to impartiality.

Complaints about a fellow worker should be taken to that person's supervisor. If the situation is not handled satisfactorily take it to that
supervisor's direct supervisor or take it directly to the President.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. When a risk has been identified, this will be added to the management review. All efforts to eliminate and prevent future will be communicated and addressed by the management team.

4.2 Confidentiality

BCS shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

Great care shall be taken to protect the confidentiality of our clients.

No information about one client shall be shared with another client without expressed written authorization specific in the scope of what information is to be shared to whom, how, and when.

If reports are to be used as samples, care shall be taken to eliminate all reference to the client and specific information related to the client. Whenever possible use BCS as the example client.

Under no circumstances are records of one client to be shared with another client without prior approval from the client whose data will be shared.

Ensure that emailed information is being sent to the right person

On-site Requirements: All on-site operations are subject to the same requirements as those of the permanent laboratory.
Once on-site operations are complete all data shall be secured and held confidential prior to completion and formal submission to the client.
Company data shall not be stored, permanently or temporarily, at any of its clients' locations

4.2.2 When BCS is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

4.2.5 For Boise Calibration's policy regarding customer's confidential information and proprietary rights, see the *Confidentiality Policy (POL-02)*. The procedure for instructing new employees in the quality system and requiring them to sign the *Confidentiality Agreement* is found in the *New Hire Introduction Agenda*.
A signed copy of the laboratory's *Confidentiality Agreement* can be found in each employee's personnel file.
The procedure for protecting the electronic storage of results is given in the *Data Protection and Backup Procedure (PRO-13).*
The procedure for protecting customers' confidential information during electronic transmission of results is given in the *Electronic Transmission Procedure (PRO-15)*

5 Structural Requirements

5.1 Boise Calibration Service Inc. is incorporated as a corporation in the state of Idaho and is headquartered in 7482 Lemhi Street, Boise, Idaho, USA, and shall operate in a legally responsible manner for all of its activities. Our business plan details the specifics of our corporation.

5.2 BCS's President, Quality Manager (QM), and Technical Manager (TM) have the overall responsibility for the laboratory. Each laboratory has a lead, who has responsibility of those labs.
The QM is to ensure that the management system related to quality is implemented and followed always.
The Management Team to ensure that all personnel are free from any undue internal and external pressures and influences that may adversely affect the quality of the calibrations.
All employees are to avoid involvement in any activities that would diminish confidence in the competence, impartiality, judgment, or operational integrity of themselves or the Company.
The Technical Manager to ensure adequate supervision of calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each calibration and with the assessment of the calibration results.
Key personnel are to have deputies for their duties, and to see that those deputies are capable of carrying out those duties.
Each Manager ensures that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

5.3 BCS Shall define and documents the range of laboratory activities for which it conforms with 17025.
The capabilities of the lab are notated, but not limited to, in the scope of calibration. This is assessed and validated by A2LA
Calibrations performed by BCS that are not listed on the scope of accreditation must still conform and meet the guidelines put forth in 17025.
Calibration performed on the behalf of BCS shall be indicated on the certificate, and certificates will show that these were not performed under our scope.

5.4 All Activities performed by BCS, including customer service, calibration, and consulting, shall be carried out as to meet the requirements of ISO 17025:2017, customer requirements, regulatory authorities, and recognizing organizations. This is applicable to all work performed at BCS's location and sites away from its location, including customers facilities.
It is the responsibility of every technician and support personnel to carry out their work in a way that meets the requirements of ISO: 17025:2017 and the customer's requirements

5.5 BCS Shall have documentation for the structure of its organization and management, as well documentation of the responsibilities, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of laboratory activities. See a) Organizational Chart, and b) Job Description Manual, and c) Docstore.
Management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
Customer Complaints will be researched and resolved by the Quality Manager.
If it is determined to be needed, set up CARs (Corrective Action Requests) with realistic time frames for all systemic problems.
Document need for re-evaluation on next regularly scheduled audit for CAR items.

The quality documentation shall be available for use by all laboratory personnel. This manual has been prepared to explain our commitment to good professional practices and quality of calibration services and shall be kept up to date.

5.6 The QM is responsible for the implementation of maintenance and improvement of the management system. This includes identification of deviations from the managements system and reporting to management team on the performance of the management system and any needed improvement.

The TM is responsible for deviations from the management system in regard to technical operations to the management system or from the procedures for performing laboratory activities. TM is also responsible for ensuring the effectiveness of laboratory activities.

Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

All employees are responsible for initiation of action to prevent or minimize deviations, whether by their actions and then reporting to the QM, or by informing the QM/TM of the deviation so that it may be resolved.

Identified deviations from management system or from procedures shall be reviewed to determine level of action needed. If it is determined to be needed, set up CARs (Corrective Action Requests) with realistic time frames for all systemic problems.

5.7 BCS management team shall review the effectiveness of the management system and meeting all requirements from customers, ISO 17025, and outside organizations. This shall be done with review of internal reports and internal during management meetings. The management team will determine what changes may need to be implemented to the management system at this time, and review its changes both while it occurs and during the next meeting. Management is to ensure that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

6 Resource Requirements

6.1 BCS shall have the necessary personnel, facilities, equipment, systems, and support services needed to perform its laboratory activities.

6.2 Personnel

6.2.1 All personnel shall be competent with and work in accordance with the management system. Everyone shall avoid involvement in any activities that would diminish confidence in the competence, impartiality, judgment, or operational integrity of themselves or BCS.
BCS shall make every effort to use only permanent employees. In the event that contracted key or technical support people are used, BCS shall ensure they are supervised and competent, and that they work in accordance with the Company quality system.

6.2.2 This shall be documented in the training files for all employees. These records shall include the competency for all laboratory activities, such as; education, qualification, training, technical knowledge, skills, experience, and validation.
Records are maintained in the computer on all personnel to provide a history of training, experience, and performance on the job.

6.2.3 The training records and personnel records shall indicate the activities and competency of such of each employee. Competency shall be reviewed and approved by the appropriate level in the management system.

The management of Boise Calibration Service formulates the goals with respect to the education, training and skills of the laboratory personnel.

The training needs of the personnel at Boise Calibration Service are evaluated on an on-going basis.

For new employees a *New Hire Introduction* is conducted to familiarize the new employee with the systems and procedures employed by Boise Calibration.

For new employees and employees who change jobs a *Skills Matrix* is prepared and filed in the *Employee Personnel File.* The skills matrix identifies the training needs for the employee as the difference between the required skills for the position and the skills the employee already has. Target dates are set for each identified training need. The skills matrix is updated at the employee's annual review, see the *Employee Annual Review Agenda*.
The effectiveness of the training actions taken shall be evaluated, by means of a verbal or other form of examination, reviewing questionnaires and charting the effectiveness of training.
Technicians with training from another source will have their competency verified in a similar manner.

6.2.4 Job description, including duties, responsibilities, and authorities shall be defined. It is the responsibility of the Management team to ensure that job descriptions are kept up to date. These can be found within Job Description Manual.

6.2.5 Job Description Manual shall indicate personnel responsible for; determining the competency, selection/training/supervision/authorization of personnel, and monitoring competency.

BCS shall have records of personnel who, according to their training and competency, are authorized to perform tasks:
Determining the competence requirements;
Selection of personnel;
Training of personnel;
Supervision of personnel;
Authorization of Personnel;
Monitoring competency of personnel.

6.2.6 Authorization of personnel shall be indicated in Job Description Manual. Specific job positions shall have indicated in the manual their specific authorizations. These include; the development, modification, verification and validation of methods and procedures; analysis of results; and review and authorization of results.

6.3 Facilities and Environmental conditions

6.3.1 It is the policy of the Company to provide laboratory accommodation and environmental conditions to facilitate correct calibration performance. These shall insure that outside conditions are eliminated that could adversely affect the validity of results.

6.3.2 Temperature and Humidity maintained in each lab as follows:

Temperature:	68° ± 2°F
Humidity:	45 ± 15% RH

6.3.3 Monitoring and recording devices are located in each lab. Records are digitally stored.

6.3.4 General access to areas affecting the quality of calibration activities is limited to calibration personnel only. Access by any other employee shall be limited to: business basis or; when accessing a restroom. The air in the labs are filtered and circulated. Separation between incompatible calibration and laboratory activities is maintained by usage of specific lab areas.

6.3.5 When calibration occurs at a customers' facility (Onsite) technicians are issued a Temp/Humidity meter to monitor conditions. Environmental conditions shall be recorded at time of calibration of customers UUT.
Where the environment may affect the instrumentation, the calibration standard, the UUT, or the required accuracy or precision of measurement, the data shall be qualified on the calibration results.
Where calibrations are undertaken in a hostile or unstable environment or in an environment that may affect the

calibration results, the results of the calibration shall be documented in order to determine the effect of the environment on the performance of the calibration.

6.4 Equipment

6.4.1 BCS shall ensure the laboratory has available all items of equipment, including reference materials, required for the correct performance of calibrations and laboratory activities, and for achieving the accuracy required. BCS shall ensure that the database and all its resources are available to each technician to facilitate the calibrations necessary. BCS shall monitor the standards needed for calibrations performed in the labs and at customers facility.

6.4.2 BCS policy is to use only standards under its permanent control. In the rare event that a customers'/outside facilities equipment is needed to provide calibration, the unit will be calibrated before use.

6.4.3 BCS Standards shall be handled, transported, stored and used and maintained the following manner:

When not in use standards are to be stored in a safe and contamination free manner. Many have their own designated storage shelves or cases. Carts are available for transport and usage of standards, both for in lab and onsite calibrations.
Routine Maintenance will be performed at the time of calibration and noted on the calibration certificate.
Working standards are checked visually and for correct operation each time they are used. A calibration check is made if there is any question regarding the accuracy and/or performance of a standard.
Standards are to be stored in a manner to prevent contamination and deterioration. The use of shelves, cases, and covers shall the used as necessary.

6.4.4 BCS Standards shall be calibrated per OEM specs, and its interval logged in the database. Calibration status shall be indicated in the database and notated on the attached calibration sticker. Any notated limitation shall be indicated on the unit and in the database. Any limitations placed on BCS equipment shall be considered when selecting the equipment for use.
When equipment goes outside the direct control of the Company for any time that item of equipment will be verified before it is returned to service. For items sent out for calibration this verification will be for operational functioning.

6.4.5 Standards used for calibration shall be of appropriate and adequate capability as to achieve the necessary measurement accuracy and/or measurement uncertainty as to provide valid results or to meet customers' needs/requirements.

6.4.6 All standards used for calibration of BCS or customer ME shall be calibrated before use. Any other BCS ME that is not for the direct measurement/calibration of ME shall be marked as "Reference Only".

6.4.7 BCS shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.
Standards are reviewed for previous use in calibration. If the standard has been found to have not been used for calibration of ME in two or more years, or an extended period of time as directed by Management, the unit may be retired until it is needed again. Standard shall be calibrated again before activation and used for calibration of ME.
Calibration intervals for BCS standards shall be initially set using OEM recommendations for electronic ME, and 12-month cycle for physical/dimensional. Calibration intervals may be lengthened or shortened to ensure continued uncertainty based a) Performance Analysis b) Guardbanding c) Uncertainty Analysis. On preceding calibration results, as follows:
Lengthening Calibration Intervals: The calibration interval for a ME may be lengthened to the desired interval when one of the above methods is utilized and has proven that it is feasible to lengthen it.
Shortening Calibration Intervals: Calibration intervals shall be shortened to the desired interval when an instrument is found to be Out-Of-Tolerance (OOT) upon calibration. If one range, one value, or one function of an ME is found to be outside its tolerance limits by any amount whatsoever, the instrument shall be considered OOT. Management may shorten the calibration interval of any ME that is found to have significant defects or to be malfunctioning OOT.

Note: An instrument that fails and is returned for repair or is dropped or damaged during its certification period shall NOT be considered OOT.

6.4.8 The Calibration Certificate number, Serial number, Property number, and calibration date/due date shall be recorded on the calibration sticker, and placed in a fashion that is clearly displayed. These are also recorded in the database and calibration certificate.

6.4.9 All BCS ME that is suspect for any reason (damage, questionable operation, out of calibration, broken seal, etc.) shall be removed from service, and a verification/calibration will be performed. A Work Order may be initiated to cover the trouble-shooting and adjustment or repair necessary to correct the problem. BCS will examine the effect of the defect or departure from specified limits on previous tests and/or calibrations performed and will, in the event the ME is Significantly OOT, institute "Non-Conforming Work" procedure.

6.4.10 On BCS Standards that require intermediate checks, these checks shall be recorded.

6.4.11 Where calibrations require new correction factors, all copies of current correction factors will be recalled and the new correction factors will be issued.

6.4.12 All ME will be safeguarded, both hardware and software, from adjustments that would invalidate the calibrations. Tamper resistant seals shall be affixed to accessible controls or adjustments of instruments or standards that, if moved, would affect calibration.

6.4.13 All ME unique identifiers shall be recorded in the database. Calibration certificates, results / observations, data, dates, intervals, accuracies, and measurement uncertainties shall be recorded in the database. Reference materials, OEM specifications, and external guidelines necessary for calibration of ME shall also be recorded in the database.

6.5 Metrological Traceability

6.5.1 It is the policy of BCS to ensure that all equipment used for calibrations, or having a significant effect on the accuracy of a calibration, shall have documented unbroken chain of calibrations. These calibrations shall all contribute to the measurement uncertainty of the ME.

6.5.2 These calibrations shall be traceable to the International System of Units, SI, by a competent laboratory accredited to ISO 17025. In the case of a reference material used for calibration, certified found/actual values provided by competent lab or provider with stated metrological traceability.

6.5.3 When Metrological traceability to the SI is not available, calibration performed shall demonstrate traceability to an appropriate reference; Certified values from calibration reports/certificates from a competent supplier. The use of specified methods or standards, clearly defined, that provide measurement results relevant for intended use and that are agreed upon by all parties concerned.

6.6 Externally provided products and services

6.6.1 BCS shall use only outside support services and supplies that adequately ensure total confidence in its calibrations. BCS maintains records of all suppliers from whom we obtain critical consumables, support services or supplies which affect the quality of calibrations.

6.6.2 BCS shall define, review, and approve externally provided products and services by performing the following:

Register of sub-contractors
Boise Calibration Service maintains a *Sub-contractor File* on each subcontractor that it uses for calibrations. This file contains the record of the evidence of the sub-contractor's compliance with ISO/IEC 17025, i.e. evidence of accreditation.

Purchasing services and supplies
The *Outside Support Services and Supplies List* defines the scope of services and supplies covered by the provisions in this section.

Selection and purchasing of services and supplies
The *Use of Outside Support Services and Supplies Policy (POL-08)* defines the measures put in place for selection and purchasing of services and supplies to ensure that the quality of these services and supplies is adequate to sustain confidence in Boise Calibration's calibrations.

Consumable materials used for the technical operations of Boise Calibration Servicethat can affect the results of calibration are identified in the *Outside Support Services and Supplies List*. The *Consumable Materials Procedure (PRO-14)* provides details of how these Materials are purchased, received and stored.

Verification of services and supplies

It is the policy of Boise Calibration Service to require purchased equipment, Materials and services to comply with the specified requirements.

Boise Calibration Service will, wherever possible, ensure that purchased equipment and consumable Material are not used until they have been inspected, calibrated or otherwise verified as complying with all standard specifications relevant to the calibrations concerned.

Purchasing documents for services and supplies

The *Consumable Material Procedure (PRO-14)* provides details of how the purchasing documents are issued, reviewed and approved for technical content.

Evaluation of suppliers

The *Outside Supplier File* contains records of all approved suppliers from whom Boise Calibration Service obtains support services or supplies required for calibration, including records of evaluations of the suppliers.

Products and/or parts ordered from a vendor shall be inspected to verify that it matches order requirements

Units coming back from calibration will be inspected to verify unit matches vendor packing slip and BCS PO. Units and accompanying paperwork/certificates will be reviewed to insure required work and calibration were performed correctly. If the unit is back from repair, unit will be returned to technician for re-calibration and verification that repair was completed and unit is functioning within tolerance.

6.6.3 BCS POs shall contain all relevant information to properly communicate the requirements of its vendors. For parts or supplies, this information must involve data describing the product. This may be a part number, type, class, grade, or other technical information in order to ensure precise identification for the vendor. A PO for the purchase of new equipment must contain information about the unit(s) being ordered. This includes Make, Model, and brief description. If unit is being purchase with calibration, the appropriate calibration level and acceptance must be indicated. If the unit is being sent to vendor for repair or adjustment, the PO must include units Make, Model, SN and brief description. It may also indicate problems found with the unit.

7 Process Requirements

7.1 Review of requests, tenders and contracts

7.1.1 BCS shall review all calibration and/or repair requests, tenders or contracts from customers in the following manner:

Review of customer documents shall include requested calibration level, calibration interval, unit(s) being sent in, specific requests, known issues with unit(s), and any other information on document. Current customers with already approved terms for all of their calibrations have been recorded into their customer file, and will be used as the equipment is received. Any new information from a current customer on their documentation supersedes that of previous.

ME found to be within our capabilities will logged into the database with Make, Model, description, calibration levels available, procedure, accuracy's, and assigned lab.

ME not within our capabilities will be logged into the database similarly, notating in the procedure that it is a vendor calibration.

When calibration or repairs are to be performed by an external vendor, the customer will be notified via automatic email. If costs for external calibration/repair/evaluation fees are known, customer will be informed before unit is sent out. Approval for sending the unit will be received before sending the unit to the vendor.

Customer requested levels of calibration shall be reviewed. This is to occur at a) the customer base level for all of their equipment. This is to be put into their customer notes, all tools updated as needed. b) at time unit is sent in for calibration. New requirements supersede previous and will be logged at time of calibration/request.

7.1.2 If a customer has specified a method or procedure to be used to calibrate their ME, this method or procedure will be verified to be valid. Validity is based upon the appropriateness for the intended use by; range, accuracy, uncertainty, linearity, repeatability, sensitivity, or date of method. If customer requested method/procedure is found to be inappropriate, customer will be informed and offered method that is valid for intended use.

7.1.3 Valid Customer requested standard(s) to be used for calibration of their ME, standard will be reviewed to be relevant to the calibration to be performed. These shall be indicate on the certificate.
BCS uses Simple Acceptance as a decision rule on certificates. When customer specifies a specific decision rule, other then Simple Acceptance, to be used for the calibration of their ME, the decision rule will be reviewed to be within capabilities. If within capabilities this will be agreed upon by both parties, customer requested decision rule will be notated in the workorder, and applied/commented on the cert.

7.1.4 All requests, tenders, and purchase orders will be reviewed prior to acceptance for calibration. Deviations from customer request or tender from contract will be determined if any impact on the integrity of the laboratory or the validity of the calibration of ME. Work will commence upon acceptance from both BCS and customer.

7.1.5 Deviation from agreement shall occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.

7.1.6 If the client wishes to amend or modify the Purchase Order after receipt of the ME, or after work has commenced, this modification shall be documented and filed in the client file and the Purchase Order Amendment shall be subjected to the same review process as the Purchase Order. These amendments shall be communicated with all affected personnel.
Technical amendments will be communicated to the technician, and modified in the database.
Non-Technical amendments will be communicated to the affected department and modified in the database.

7.1.7 Customer may request to observe the performance of the calibration of the ME. This request shall be reviewed, and reasonable access to the lab and the technicians involved in calibration shall be made available.

7.1.8 Records of requests, tenders, contracts, and purchase orders shall be maintained. This includes any significant changes, and pertinent discussions with customer relating to the customers' requirements, requests, and the results of BCS activities.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 BCS shall use appropriate procedures and methods for all calibration it performs. Calibrations requiring measurement uncertainty will have those values calculated and added to the database.

7.2.1.2 All methods, instructions, manuals, standards, and procedures that are necessary to calibrate ME shall be stored and readily available in Technicians performing calibration shall only have access to current revisions of procedures in DocStore.
When necessary updates, modifications, or additional details will be supplemented to achieve correct and current calibrations.

7.2.1.3 BCS shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

7.2.1.4 Unless specified by the customer, BCS will select an appropriate method from its In-House list of procedures or shall use standard methods that have been published either in international, regional or national standards by reputable technical organizations or the manufacturer.

7.2.1.5 Procedures will be validated before use in calibration of ME. The validation shall be appropriate for the intended calibration; e.g., range, accuracy, uncertainty, linearity, repeatability, sensitivity, selectivity of method, robustness against external influences, etc. and recorded in Docstore. If method is revised by the issuing body, validation shall be repeated to the extent necessary.

7.2.1.6 When a procedure or method needs to be created, a technician who has been authorized shall be assigned to develop procedure. Procedure will be validated and approved by those who are authorized before being added to DocStore. As with all procedures, review will occur to insure proper calibration is valid. Procedures to be revised as needed.

7.2.2 Validation of methods

7.2.2.1 BCS will validate non-standard methods, Company developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that they are fit for their intended use.
Determination on the performance of a method should be one of, or a combination of the following:
Calibration using reference standards or reference materials.
Comparison of results achieved with other methods.
Inter-laboratory comparisons.
Systematic assessment of the factors influencing the result.
Assessment of the uncertainty the results based on scientific understanding of the theoretical principles of the method and practical experience.
Testing of method to verify robustness using controlled parameters

7.2.2.2 When changes to a procedure are required, influences shall be determined and if found affecting original validation, a new validation shall be performed.

7.2.2.3 The performance of procedures shall be relevant to the customers' needs. Characteristics can included, but not limited to: The range, accuracy, the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability or reproducibility, robustness against external influences, cross-sensitivity against interference from the matrix of the object.

7.2.2.4 BCS Shall record validation of procedure in DocStore. Validated Procedures shall indicate their intended use, specifications to be used, performance characterizations from method. Results obtained will be notated in the units being calibrated model details/datasheets.

7.3 Sampling

N/A - BCS does not provide Sampling services

7.4 Handling of test or calibration items

7.4.1 BCS shall handle calibration items in the following manner:

Customers calibration ME is handled in such a way as to prevent damage, protect the integrity of the calibration and protect the identity and ownership of the item from the time we receive it until it is returned to the customer. All precautions shall be used to avoid deterioration or damage to the calibration item during transportation, receipt, handling, storage, retention and/or disposal. Special customer handling will be notated and followed.
ME handling is facilitated by the use of wheeled carts and shelves for moving and staging equipment in process. Shelving for ME in each status awaiting action must have easy access and must allow adequate space. Workbench surfaces shall be of suitable material to prevent damage during calibration and repair. Storage at each status shall be held secure, for such reasons of record, safety, value, and security.
Preparations for shipment using each method is organized to meet the type of equipment, distance, and carrier used when shipping is required. Shipping to use proper materials such as bubble pack, foam blocks, foam-in-place, and boxes to meet individual packing requirements. Shipping using external shipping carriers shall followed, including the space and amount of material surrounding ME(s), and type/quality of box to be used.

7.4.2 BCS shall record, upon receipt of the calibration item, the identity of the ME(s) and enter into the database. Identification includes but not limited to customer, and the ME SN, Make, Model, and Property#. This identification shall be retained throughout the life of the ME. Database is capable of ensuring that items cannot be confused physically or when referred to in records or other documents. The database also accommodates subdivision of groups of items and the transfer of items within and from the Company.

7.4.3 BCS shall record, upon receipt of the calibration item, the identity of the item, the condition of calibration item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration method. If any of the following conditions exist, BCS is to contact the customer for further instructions: a) There is any doubt as to the suitability of an item for calibration. b) When the item does not conform to the description provided. C) When the calibration procedure is in doubt. d) When there is any obvious physical damage. e) When the calibration procedure departs from standard procedure. Decisions made by the customer will be recorded.

7.4.4 Where a calibration item is to be stored or conditioned under specified environmental conditions, those conditions are to be maintained, monitored and recorded.

7.5 Technical records

7.5.1 BCS shall ensure that all technical information is correctly collected and recorded. This technical information stored into the database is used to facilitate and identify all factors that occurred during the calibration, enabling the repetition or replication of the calibration as closely as possible to the original. Technical information stored includes technician, standard, environmental, data taken during calibration, observations/comments, and event log.

7.5.2 Amendments to technical records will be recorded, indicated by "Rev X", where x based on the revision version. Original certificate number maintains the same. Amended information will be detailed in the comments section of the certificate.

7.6 Evaluation of measurement uncertainty

7.6.1 BCS shall identify all contributors to the measurement uncertainty of a ME during its calibration. All contributors shall be taken into account using appropriate method of analysis. Guidelines for the various methods of calculating measurement uncertainty can be found in such documents: International Guide to the Expression of Uncertainty (GUM), ANSI/NCSL Z540, and A2LA.

Customers requesting the uncertainties to be calculated by a different method will be reviewed for validity, and if it can be produced by BCS during the calibration. All uncertainties reported shall be as expanded uncertainties using a coverage factor of k=2 to approximate the 95% confidence level.

7.6.2 All calibrations requiring Accredited calibrations, including BCS standards, shall have the measurement uncertainties evaluated.

7.6.3 N/A - BCS does not provide testing.

7.7 Ensuring the validity of results

7.7.1 BCS shall ensure the validity and quality of the results by performing the following:

Calibration methods, performance and results will be monitored. Data collected during calibration shall be recorded in the database, linked to the ME and specific calibration instance/certificate. Data can then be used so that any trends may be detectable, and when practical, statistical techniques shall be applied to review the results. These methods shall be reviewed using, but not limited to:

ME will be retained and unit will be recalibrated by another qualified technician to analyze performance and results;
Correlation of results for different characteristics of an item, where appropriate. If one parameter is out the other parameters will be given closer attention;
Analysis of quality control data where such data indicates a potential problem or nonconformance;
Use of alternative standards that has been calibrated to provide traceable results;

7.7.2 BCS Shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This will be planned and reviewed and shall include but not limited to:

Participating in a sponsored proficiency test whenever possible;
When a sponsored proficiency test is unavailable participation in inter-laboratory proficiency tests will be used;
When inter-laboratory tests are unavailable or results would not be relevant, an intra-laboratory test may be developed.

7.7.3 BCS Shall be analyzed and used to control and improve its capabilities and activities, where applicable. If the results of the analysis of the data from the monitored activities are found to be outside the criteria of the method, appropriate action shall be taken to prevent incorrect results and ensure that they do not occur again.

7.7.4 Results of Proficiency tests will be submitted to A2LA within a month of Final report being received.

7.8 Reporting of results

7.8.1 General

7.8.1.1 Certificate and results shall be reviewed and authorized prior to release.

7.8.1.2 BCS shall accurately, clearly, unambiguously and objectively report the results of each calibration on a Certificate of Calibration. The certificate shall include all information agreed upon with the customer and necessary for the interpretation of the results and all information required by the method used.

7.8.1.3 Upon customer request, a simplified or truncated certificate can be issued. These certificates shall still retain all unique identifiers required. The amount of information provided is dependent on the requested amount by the customer.

7.8.2 Common requirements for calibration certificates

7.8.2.1 The minimum information on a calibration certificate or report from an outside supplier to meet BCS requirements is:

a) title, "Certificate of Calibration";
b) Name and address of BCS Calibrations;
c) If calibration occurred at customers location the certificate will notate "Onsite" on the certificate;
d) Unique identification of the certificate by number;
e) Name and contact of customer requesting calibration. If requested, the certificate can be issued to a 3rd company, the 3rd companies name and contact information will be issued on the certificate;
f) Identify the calibration procedure used;
g) Unambiguous identification of the item calibrated, including description and condition of unit;
h) Date of receipt of unit and date of performance of calibration;
i) Calibration results with units of measurement, as applicable;
j) Statement that results on certificate are for only the UUT and that instance of calibration;
k) Identification of the person authorizing the calibration;
l) Clear identification of the end of the document;
m) A statement that the document shall not be reproduced, except in full, without the written approval of the laboratory;
n) Any deviations from, additions to or exclusions from the calibration method;
o) Any special limitations of use;
p) An Indication of any Out-Of-Tolerance condition. Level one calibration remarks can include direction and a percentage off from nominal. All other levels data will be provided;
q) Identification the standards used during the calibration, listing the model number, description, and serial number;
r) When a subcontractor performs calibration it will be clearly stated.

7.8.2.2 BCS is responsible for all information on the certificate, unless it has been provided by the customer or an outside vendor. External data shall be clearly identified, including a statement that external data can affect the validity of the results

7.8.3 Specific requirements for test reports

N/A - BCS does not provide test reports.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 BCS shall provide additional information on certificates, where relevant, that are necessary for the interpretation of the test results including;

a) The measurement uncertainty stated in the same unit as that of the measurand or in a term relevant to the measurand;
b) Environmental conditions at time of calibration;
c) Evidence that the measurements are traceable, such as a statement of traceability to SI
d) Before and after data if the unit is adjusted or repaired, when available;
e) A statement that the instrument was calibrated and specifications to which it was calibrated;

7.8.4.2 N/A - BCS does not provide sampling

7.8.4.3 Calibration interval listed on certificate is from agreed upon value and date from customer. Calibration interval increases after ME has been calibrated and returned to customer shall be check for validity. Interval increases from customer on ME that is already past due date will be declined.

7.8.5 Reporting sampling

N/A - BCS does not provide sampling

7.8.6 Reporting statements of conformity

7.8.6.1 BCS uses Simple Acceptance rule on all certificates unless requested by the customer, and is indicated in the results on the certificate.

7.8.6.2 If a customer requests that a different statement of conformity is used for the calibration, it will be reviewed to determined if BCS can accommodate the requested conformity. If a different conformity is used the certificate shall clearly identify:
a) the specified results the statement of conformity applies;
b) the specifications, standards or parts thereof are met or not met;
c) the decision rule applied

7.8.7 Reporting opinions and interpretations

Opinions and interpretations are not offered to clients, this is for test laboratories only

7.8.8 Amendments to reports

7.8.8.1 When an issued certificate needs to be changed or amended, any change of information from the original shall be clearly identified and when reasonable the reason for the change included on the amended certificate.

7.8.8.2 Amended certificates shall only be issued as an additional document, not an updated original, and shall be indicated on the certificate as "Rev A" or similar alpha numeric.

Amended certificates shall meet all the requirements of the of the original certificate.

7.8.8.3 If a cert cannot be amended, and new certificate shall be issued with all requirements of this document, and shall reference the original calibration.

7.9 Complaints

BCS shall address and resolve all customer complaints whether solicited or not.

7.9.1 BCS has a documented process to receive, evaluate and make decisions on complaints.

7.9.2 Complaint process is available upon request. If upon review of a complaint it is found to relate to a lab, the complaint will be assigned to the lab lead for investigation. Lab lead will determine activities involved and how to deal with it. BCS shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 Complaints can be logged into the database by all employees and by customers logging into their customer portal. The Quality Manager will review each complaint and determine who is best suited to handle and respond. Complaint will be reviewed by the person(s) assigned, and all evidence will be gathered and verified. All individuals involved with complaint will be noted. All complaints shall be permanently logged. If during the process it is determined that a corrective action needs to be initiated, it shall be issued by the Quality Manager.

The outcome of the complaints reviewed by individual not involved with the original activity under review for complaint. Upon approval, outcome shall be reported to the complainant whenever possible.

7.9.4 BCS shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming work

7.10.1 When work does not conform to the procedures of BCS or the agreed upon requirements of the client, BCS shall perform the following:

Promptly evaluate the significance of the error of the results, take prompt remedial action and, where applicable, take corrective action. All BCS employees have the authority and responsibility to stop non-conforming work.

The QM shall immediately be notified and shall perform an evaluation of the significance of the impact on the validity of the calibration results. If it is determined that the possibility of miss-calibration of BCS Standards exists, a reverse trace will conduct a record search for client instruments that may be affected. Clients whose instruments are found in this category will be notified to send their unit back for calibration. This notification will start with either the most recent calibration or the one likely to have the most impact. If these units show no impact other customers will not be notified.

The QM or the OM shall authorize resumption of work once the nonconformity is resolved

7.10.2 All non-conformance and actions thereof shall be recorded and maintained.

7.10.3 A Corrective Action Report (CAR) will be initiated when the non-conformances indicate a problem with the quality system, ore where the evaluation indicates a doubt about the compliance of the laboratory's operations with its own policies or procedures. This will be initiated by the QM, and issued to the appropriate roles.

7.11 Control of data and information management.

7.11.1 BCS and all employees shall have access to all data and information needed to perform their/its functions and activities.

7.11.2 BCS uses third party programs such as Rbase for its database, and Excel for functions outside of database abilities. Where necessary, OEM operating and recording software for standards being used as standards during calibration. Any changes or updates must be authorized by management before implementation.

7.11.3 BCS information system shall control and monitor:
a) Database access is limited to employees with individual logins. Each employee has their own password, and the database is set up that restrictions are in place so that employees only have access to the information needed to do their functions
b) Restrictions to data is per job function, as per indicated by levels of access each employee has in the database. Information cannot be tampered with due to restrictions. Required updates and revisions are notated. Database and digital files are on a server that is RAID based to prevent loss. Additionally, database is backed up daily, and backups and files are stored on a local secondary server. Backups and files are routinely transferred to an external hard drive for transfer to an offsite hard drive
c) Paper records are stored so as to prevent degradation and loss due to environmental. Paper records are not altered from original. New information is stored with originals. Paper records are stored for a minimum period of 5 years.
d) If for any reason there is a loss of records, the event will be logged and reviewed for the appropriate immediate and corrective actions. This process will be handled in the same manner as a CAR.

7.11.4 External backups are maintained in similar manner to originals maintained on BCS Servers. External hard drive has no external access to prevent loss and tampering.

7.11.5 Any calculations performed will be done using database or external software that has been shown and verified to be appropriate and correct.

8 Management System requirements

8.1 General

BCS's management shall strive, at a minimum, to address the follow in regard to the laboratories management system:
a) Management system documentation
b) Control of management system
c) Control of records
d) Actions take to address risks and opportunities
e) Improvements
f) Corrective Actions
g) Internal audits
h) Management reviews

8.2 Management system documentation

8.2.1 BCS's policies are designed and meant to cover and fulfill the purpose if ISO/IEC 17025:2017. BCS shall establish, document, and maintain said policies. These policies shall be acknowledged and implemented at all levels of the laboratory. It is the responsibility of every technician and support personnel to carry out their work in a way that meets the requirements of ISO: 17025:2017 and the customer's requirements.

8.2.2 These policies shall also address the competence, impartiality and consistent operation of the laboratory. The factors used to evaluate included but are not limited to:
How well we are meeting our definition of quality;
The latest regulatory requirements;
Our client's special needs;
Effectiveness of latest systems corrections;

8.2.3 Management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness. System shall be reviewed and discussed for current development and structure, and future needs during management reviews.

It is the QM's responsibility to ensure that the quality system is implemented and followed always. The OM will assist in this process.
All BCS employees have the responsibility to be familiar with the quality documentation and implement the policies and procedures in their work.
All management is responsible to be in compliance with ISO 17025.
All management shall communicate to the organization the importance of meeting customer as well as statuary and regulatory requirements.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system. The elements of the Company's quality system are documented in this Quality Manual and other related documentation, consisting of:
Quality Manual.
Job Description Manual.
Employee Manual

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities. Availability of all authorized editions of quality documents through DocStore.

8.3 Control of management system documents

8.3.1 BCS Shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventative actions.

8.3.2 Documents to be reviewed and approved by authorized employees before being uploaded to DocStore, where documents can only be viewed or printed. Authorized personnel include but are not limited to Quality Manager, Technical Manager, and Lab Leads. Documents shall be reviewed and updated as necessary, such as a correction by the OEM to a previously released manual. Changes and current revisions shall be identified in DocStore. Only current revisions can be viewed from Docstore. All documents have a unique identifier in DCN numbers, and file ID. Physical copies of old revisions shall be removed and destroyed.

8.4 Control of records

8.4.1 BCS Shall retain legible records to demonstrate the fulfillment of the requirements of 17025.

8.4.2 BCS shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records.
All records, certificates and reports will be safely stored and held secure and in confidence to the client for a minimum of five years. After that point, physical copies shall be destroyed. All documents held in database and DocStore will be held indefinitely.
Access to the database shall be by password only. BCS employees receive a unique password created and stored in the database.
Database data shall be backed up daily and stored on the server. Server is backed up weekly. Offsite storage is done by manual backup of server which is then hand carried to external facility.
The DocStore program is set up to be read or print only. Modifications to documents in the DocStore program can only be made by complete revision updates.

8.5 Actions to address risks and opportunities

8.5.1 BCS shall consider the risks and opportunities associated with the laboratory activities in order to;

a) Give assurance that the management system achieves its intended results;

b) Enhance opportunities to achieve the purpose and objectives of the laboratory;

c) Prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) Achieve improvement.

8.5.2 The laboratory shall plan:

a) Actions to address these risks and opportunities;

b) How to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

8.6 Improvement

8.6.1 BCS shall strive for continuous improvement in the effectiveness of its management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management reviews. Audit results will be reviewed by the President at the conclusion of each Audit.

During quarterly management meetings, the following will be reviewed:
Quality Objectives
Analytical data collected by the database
Corrective and preventative actions
Management reviews

Every employee can log an anonymous suggestion for improvement in the database. They can encompass any issue the employee wishes to raise. These shall be reviewed, and outcome indicated in the database.

8.6.2 BCS customers are encouraged to provide feedback, both positive and negative, on the quality of Company work, workmanship, and customer service. Surveys are sent out automatically to our customers, and surveys are available to be completed on our website and through customer portal.

8.7 Corrective Actions

BCS shall initiate corrective action any time nonconforming work or departure from policies or procedures in the quality system has been identified. Required changes will be documented and implemented.

8.7.1 In the case of non-conformance, BCS will promptly evaluate the significance of the error of the results, take prompt remedial action and, where applicable, take corrective action.

If the non-conformity is because a BCS standard was found OOT, the QM shall immediately be notified and shall perform an evaluation of the significance of the impact on the validity of the calibration results. If it is determined that the possibility of miss-calibration by BCS ME exists, a reverse trace will be performed to search for client instruments that may be affected. Customers whose instruments are found to be affected by the non-conformance will be notified to send their unit back for calibration. This notification will start with either the most recent calibration or the one likely to have the most impact. If these units show no impact other customers will not be notified.

8.7.1.1 Activities involved with non-conformance shall be ceased until the non-conformance has been resolved. A CAR will be created and issued to the responsible party for the recording of the non-conformance. Any employee involved with the non-conformance is responsible for assisting in the analysis of the problem and in determining effective corrective action.

Evaluate the effects of the non-conformance. Determine the level of non-conformance. Verify how the non-conformance has affected or shall affect activities, and remedy the consequences.

8.7.1.2 The QM shall utilize any resource available to evaluate the need/course of action to eliminate the cause to ensure it does not recur or occur elsewhere.

Review and analyzing nonconforming items directly and recording information. All findings and data found during the investigation shall be logged into the CAR

Determine and identify causative conditions or factors (root cause); i.e., human error, equipment failure, system failure, failure to follow procedure.

Determine if there is possibility that similar non-conformance exists or could occur. If it is determined that there is the possibility of similar, the process will be repeated per each incident.

8.7.1.3 Implement any action needed;
Once root cause is determined a recommended corrective action shall be selected and offered in the CAR. This will be reviewed for acceptance and resolution by the QM. If unacceptable it will be returned for further analysis. Once acceptable, the Quality Manager shall approve and authorize implementation.

8.7.1.4 Review the effectiveness of any corrective action taken;
Quality Manager will review implementation of corrective action as reported on the CAR for its effectiveness and practicality

When satisfied that the solution is permanent and effective, the QM will complete the "Follow-up" section of the CAR form.

8.7.1.5 Update risks and opportunities determined during planning, if necessary;

8.7.1.6 Make changes to the management system, if necessary.
When changes to the system have occurred due to a nonconformance that casts doubts on the Company's ongoing compliance with its own policies and procedures the QM shall audit the appropriate areas with the next internal audit.

8.7.2 Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

8.7.3 BCS Shall document and retain record of any corrective actions. All CARs are entered into the database, logged by chronological order and assigned a unique number. These records shall include:

Nature of the non-conformance, complaint, issue;
Assigned lab/personnel;
Subsequent actions taken;
Results of follow-up.

8.8 Internal Audits

8.8.1 BCS shall periodically audit its facilities, processes and personnel to verify that operations continue to comply with the requirements of the quality system, and to IEC/ISO 17025:2017.

8.8.2 Boise Calibration Service periodically conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and ISO/IEC 17025:2017.

Planned audits are documented in the *Internal Audit Plan*.

Audits are planned such that all elements of the quality system, including the calibration activities are audited at least once per year. It is the responsibility of the **Quality Manager** to plan and organize audits as required by the *Internal Audit Plan* and as requested by management. Wherever possible, the audits are carried out by trained and qualified staff that is independent of the activities being audited. The audits are based on the AB "Assessor Checklist for Calibration Labs" and are designed to determine:

- Whether procedures described in the quality system are being followed;
- Whether quality system objectives are being achieved;
- Whether designated duties are being carried out satisfactorily; and
- Whether there are opportunities for improvement.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of Boise Calibration's calibration results, Boise Calibration Service will take timely corrective action, and notify clients in writing if investigations show that the laboratory results may have been affected.

Completed audits are documented in the *Audit Documentation File*. The documentation includes the area of activity audited, the audit findings and corrective actions that arise from them.

Auditing shall be by trained and qualified staff or outside independent vendor, proof of audit training shall be maintained. Auditors shall be independent of the aspect of the audit. All staff who assist in the audit should be trained in the aspect of the audit. Audits shall be reviewed by President.

Document and retain all audit findings and any corrective actions that arise from them. All discrepancies will be recorded and reviewed by management. All systemic failures shall be documented for corrective action. Corrective Actions will be reviewed on a regular basis to determine if corrective action has been carried through and if it was effective. Follow-up activities shall verify and record the implementation and effectiveness of the corrective actions taken.

8.9 Management reviews

A management review of the quality system is performed annually; see *Internal Audit Plan*, to ensure that the quality system continues to be suitable and effective and to introduce any necessary changes or improvements.

The management reviews follow a set agenda, see *Management Review Agenda*.
The minutes of completed management reviews are documented in the *Management Review File*.
Corrective action requests initiated as a result of the management reviews are documented in the *Corrective Action Log*.
Follow-up audit activities verify and record the implementation of the corrective action within an appropriate and agreed timescale, as well as the effectiveness of the corrective action taken.

References

POL-01 Quality Policy
POL-02 Confidentiality Policy
POL-03 Gifts and Gratuities Policy
POL-04 Internal Complaint Policy
POL-05 External Complaint Policy
POL-08 Use of Outside Support Services and Supplies Policy
POL-09 Acceptable Activities Policy
POL-10 Nonconforming Calibration Work Policy
POL-11 Corrective Action Policy
PRO-01 Quality Documentation Maintenance and Distribution Procedure
PRO-03 Work Flow Procedure
PRO-05 Feedback and Corrective Action Procedure
PRO-06 Complaint Procedure
PRO-13 Data Protection and Backup Procedure
PRO-14 Consumable Material Procedure
PRO-15 Electronic Transmission Procedure
PRO-16 Activity Evaluation Procedure
PRO-17 Externally Generated Quality Documentation Maintenance and Distribution Procedure
PRO-18 Maintenance of Electronic Documents Procedure
PRO-19 Preventive Action Procedure
PRO-20 Record Control Procedure
Technical Manager Job Description
Quality Manager Job Description
Technician Job Description
Administrative Assistant Job Description
Confidentiality Agreement
Internal Audit Plan
Proficiency Plan
Management Review Agenda
New Hire Introduction Agenda
Quality System Training Form
Quality Documentation Update Form
Quality Document Master List
Outside Support Services and Supplies List

Corrective Action Log
Technical Manager Personnel File
Quality Manager Personnel File
Obsolete Documents File
Sub-contractor File
Outside Supplier File
Audit Documentation File
Management Review File
Customer Survey Form
Work Flow Process Chart- RFQ
Work Flow Process Chart- On-Site
Work Flow Process Chart- Work Flow Processes
AB Specific requirements

8.9.1 BCS Shall plan for senior management to annually review the quality system and all audits of the quality system.

8.9.2 All input from those in attendance shall be noted and responsibilities assigned for action items. All members will initial that they attended the meeting and participated in the discussion. The agenda for the meeting will include the following:
Suitability of policies and procedures;
Reports from managerial and supervisory personnel;
Outcome of recent internal audits;
Corrective and preventative actions;
Assessments by external bodies;
Results of inter-laboratory comparisons and/or proficiency tests;
Changes in volume and type of work;
Customer Feedback;
Complaints;
Recommendations for improvement;
Other relevant facts, such as quality control activities, safety, resources and staff training.

8.9.3 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale. Resources that have found to be needed for the continued activities of the lab, or needed improvements, shall be researched and implemented at best course of interest for BCS.

8.10 Advertisement of accredited laboratory status

It is the policy of this company to affect control over the intellectual property of the Accrediting body (including but not limited to: Titles, Logos, copy written documents/software, proprietary information, patented designs, etc), released by the Accrediting body for the use of their Accredited Entities, to use/disseminate said intellectual property in a manner consistent with the policies, procedures and Legal precepts set forth by the Accrediting body regarding said dissemination of intellectual property released by the Accrediting body for the use of their Accredited Entities.

8.10.1 Use of the A2LA Logo on Calibration Certificates/Reports:
In any instance where the Company uses the A2LA accredited Logo to endorse Calibration Certificates/Reports/Results, the company shall ensure the Logo is accompanied by the A2LA Certificate number(s).

The "A2LA Accredited" Logo, including "Calibration 723.01", may be displayed on all certificates and reports that contain exclusively results from activities that have been carried out within the Company's official A2LA Scope of Accreditation.

The Company shall ensure the A2LA accredited Logo will not be used on Certificates, Reports, or results that are not included in the Company's existing scope of accreditation.

When a Certificate, Report, or Result contains both accredited and nonaccredited parameters, the Company shall ensure the non-accredited parameters are clearly identified as such. This will be accomplished, by placing a check mark by the accredited parameter and note that items with the check are accredited.

In any instance where the Company issues a Calibration Certificate, Report or Result with the intent that said Certificate, Report or Result meets the requirements of the A2LA traceability Policy, the Company shall ensure that Certificate, Report or Result contains the A2LA Accredited Logo and A2LA certificate number.

Non-accredited Calibration Certificates, Reports or Results are distinguished from accredited Calibration Certificates, Reports or Results by exclusion of the A2LA accredited Logo. There shall be nothing in the reports, certificates or in any attachments or other materials which implies or may lead any user of the results or any interested party to believe that the work is accredited when it is not.

In any instance where the A2LA name and/or Logo is used/disseminated by BCS, it shall at a minimum be accompanied by the word “accredited”.

In any instance where the “A2LA accredited “ Logo is used/disseminated by BCS it shall ensure the Logo maintains its form. Therefore, when the Company re-produces the Logo, the Logo is allowed to assume different sizes, but the aspect ratio/geometry of the Logo must remain “as is”. It may be generated electronically as long as the prescribed formats and forms are retained.

8.10.2 The Accrediting body has the responsibility of informing BCS of the policies and procedures, changes to the policies and procedures and effective dates thereof, or any Legal precepts, changes to any legal precepts and effective dates thereof, regarding the use/dissemination of the Accrediting body’s intellectual property released by the Accrediting body for the use of their Accredited entities.

8.10.3 The Management team has the responsibility and authority of controlling the use/dissemination of intellectual property of the Accrediting body released by the Accrediting body for the use of their Accredited Entities in a manner consistent with the policies, procedures and legal precepts set forth by the Accrediting body regarding the use/dissemination of said intellectual property.

8.10.4 Current AB is A2LA but if at the time the AB is no longer A2LA, the A2LA Logo shall not be used/disseminated in any manner by BCS. The A2LA Logo shall only be used/disseminated by BCS with the name that holds the A2LA accreditation under, BCS Calibrations, Inc.

When the company promotes or provides proof of accreditation, the company shall only use the current scope of accreditation. The certificate shall be used for display purposes and to accompany the scope.

8.11 On-site Calibrations

BCS shall provide on-site calibrations with the same integrity as provided at the permanent lab. This includes ensuring that relevant parts of the quality documentation and up-to-date calibration procedures exist and are available to all staff performing on-site calibrations.

8.11.1 With exception due to the complexity, size, or accuracy of the standards to be used, all calibrations that BCS performs in lab will be able to provide onsite calibration. These limitations include, but not limited to: Ring gages, Thread (ID/OD), Wires, Cylindrical gages. Calibration of pipettes onsite is limited to the availability and calibration of customer scale during onsite (accuracy of the scale to determine the capability of the calibration). Temp and RH ME is limited to ambient per customer request unless customer has a chamber that is thusly calibrated before by BCS.

8.11.2 Maintain an up-to-date record of requested and confirmed onsite requests, and for the lab(s) involved, and a list of ME to be calibrated during onsite, via the onsite schedule.

8.11.3 Calibrations and the Certificate will indicate when a calibration is performed onsite.

8.11.4 Have approved signatories for all calibrations performed on-site, these will be the same signatories available for all calibrations.

8.11.5 Provide trained and competent personnel for on-site calibrations. Besides training on the individual calibrations technicians will be trained on the unique situations they may encounter during an onsite.

8.11.6 Ensure equipment used for on-site calibrations are fit for use and are checked prior to and directly after on-site. Technicians will acknowledge check outs prior to onsite via the Onsite Notes.

8.11.7 Ensure the environment will not invalidate the calibration status of standards used on-site. The environment shall be continuously monitored to ensure that it is stable and conducive for the type and range of calibration performed. In the event the environment is or becomes too hostile to ensure the integrity of the calibration results the calibration shall be stopped.

8.11.8 Audit on-site efforts, operations and calibrations. Onsite audits will record observations, timetables, and tasks preformed.

8.11.9 To calculate the measurement uncertainty. Measurement uncertainties will be calculated the same way they are done in house, with special attention to the effects of the environmental conditions.