National Assessment Submitted After Risk Management Training in 2015

Data Compiled 2/7/2017

Current 17025 Section Number	Identify an event or hazard that COULD impact the quality of the laboratory measurement or test results.	Combined Controls	Probability	Impact
4.1 Organization	Loss of Trained Laboratory Personnel	None	5%	100%
4.1 Organization	Weights marked as in tolerance when actually out	Code of ethics of employer	1%	75%
4.1 Organization	A metrologist is allowing weights to be marked as in tolerance when out of tolerance to save a customer money	As a part of the state organization, the metrologist is bound to the code of ethics and may be terminated	10%	70%
4.1 Organization	Loss of one or more trained metrology staff	Cross train current metrology staff, Succession planning, Early hiring when possible to train with exiting	40%	50%
4.1 Organization	Out of date organizational chart	Annual audit, Scheduled document review	30%	5%
4.1 Organization	The Lab is under the Dept of Agriculture, Quality Assurance Division, Measurement Standards Branch but requires funding from the State general fund to operate and function.	The management of the Dept of Agriculture submits testimony on the impact of the Weights and Measures program and usually gets the funding for the Measurement Standards Branch. Once in a while, when the State budget is tight, the funds are restricted and cuts to the Branch operating budget and personnel are implemented.	15%	90%
4.2 Management System	Loss of management support		10%	100%
4.2 Management System	Laboratory QMS documents not updated or maintained	Internal Audits, Management Reviews, External Assessments (NIST, NVLAP)	10%	60%
4.2 Management System	Not maintaining the QMS	Scheduled annual review	1%	10%
4.2 Management Systems	A new ISO 17025 is updated and new requirements are added to the standard.	manual and the quality management system will be also updated to reflect all of the new requirements. Internal audit will be completed to see if the requirements are met.	30%	20%
4.3 Document Control	Obsolete or not approved Documents could be used in the lab	Documents must be dated and signed before being implemented into the quality system, Documents are reviewed periodically, Documents are reviewed as part of the Internal Audi, Documents are reviewed in Team Meetings	10%	50%
4.3 Document Control	Personnel are on an outdated document	Annual Document review, Document control procedure, Annual quality audit, master list review	90%	30%
4.3 Document Control	Technician used outdated SOP for performing calibration work, The calibration was done incorrectly	Quality Manual's Master List that is used to state the current publications to be used, Prompts removal of outdated manuals and procedures	10%	25%
4.3 Document Control	Corrected calibration report	AP to specify corrections to certificates	1%	15%
4.3 Document Control	Outdated master list	Quality manager reviews library and documents desk	90%	10%
4.3 Document Control	Typo or miss identification of Calibration Reports	Standard process for naming calibration reports based on date of measurement and metrologist, Peer Reviews of any new calibration report formats and wording, Double check of reports before sending/issuing	1%	10%
4.3 Document Control	Using an outdated document	Scheduled review of documents	10%	8%
4.3 Document Control	An older version of a controlled document is use, instead of the newer version.	Controlled documents are reviewed as needed or at least annually to prevent the use of older documents being used. The "HI Document Log" file is updated and lists the latest version of the document that is in use.	9%	50%
4.4 Contract Review	Scale truck not arriving	Appointment confirmations sent to customers	3%	25%
4.4 Contract Review	Untrained employee speaking with customer	OJT and familiarity with QMS	10%	10%
4.4 Contract Review	Lifting, electrical shock	General ergonomic and office-related safety training, Properly wired and grounded equipment	10%	9%
4.4 Contract Review	A 5 gallon stainless steel test measure was tested using SOP 19 (volume transfer) instead of SOP 14.	The SAP 3, contract review procedure would be reviewed. The customer would be contacted and be informed of the differences in calibration procedures, results and calibration costs.	15%	45%
4.5 Subcontracting	Using an unapproved subcontractor	Using an approved subcontractor list	2%	68%
4.6 Purchasing and Supplier Evaluation	Purchased latex gloves from unapproved supplier	Using an approved supplier list	7%	72%
4.6 Purchasing and Supplier Evaluation	Poor, incorrect, insufficient purchase orders	Consistently work with known suppliers, SAP 15 for purchasing materials and outside calibrations	20%	60%
4.6 Purchasing and Supplier Evaluation	Supplies purchased for the lab are not suitable	Purchase supplies that are known good, Assess the supplies for suitability when they arrive, but before use	10%	51%
4.6 Purchasing and Supplier Evaluation	Invalidated supplies may not meet the required specifications for the application of use	Purchasing reagent grade supplies for a approved vendor only, Testing quality of the supplies upon use	1%	50%
4.6 Purchasing/ Supplier Evaluation	Supplier evaluation was not done on a purchase of a standard or equipment	Supplier evaluations are done prior to any purchase to see if the supplier is accedited and the purchased item will meet all of the criteria and requirements needed.	17%	50%
4.7 Customer Service	A survey monkey Customer Satisfaction survey was given to customers after calibration was completed.	SAP 12, Complaint Resolution is reviewed. All positive and negative feedback from customer surveys are reviewed. Complaints and Corrective actions are documented and reviewed in the management reviews.	5%	25%
4.7 Service to the Customer	A customer brings in more artifacts than what they are scheduled for	Having a documented schedule and appointment confirmation system, Using a laboratory policy on unscheduled items	7%	22%

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4.7 Service to the Customer	472 ; If customer feedback is not solicited and reviewed, the laboratory risks losing the business of the customers who feel ignored The overlooked issues could also impact other customers having the same issue	Conduct phone surveys randomly throughout the year Ask questions that are on the customer feedback form and document the responses, Customer feedback form is on laboratory's website and can be populated and submitted on-line The link to the survey page is included in the signature of lab staff emails, Customer feedback is reviewed twice per year during management review meetings	10%	20%
4.7 Service to the Customer	Client skeptical of test results provided by the laboratory	Client permitted controlled access to laboratory to observe retesting of the artifact(s)	10%	20%
4.7 Service to the Customer	Customer requests to observe how his or her 5 gallon test measure is calibrated	The customer is permitted controlled access to the volumetric laboratory to observe the calibration procedure	5%	5%
4.7 Service to the Customer	Client requests to observe 5 gal TM being calibrated	Client permitted controlled access to volumetric testing area by metrologist	20%	5%
4.8 Complaints	If complaints are ignored, potential corrective / preventative / improvement actions will be missed and customers may be lost	Complaints (internal and external) are initiated through the laboratory's website Complaints entered in the website are automatically transferred to the laboratory's metrology database for immediate review by appropriate lab staff, 100% of customer complaints result in C/P/I action as appropriate	10%	70%
4.8 Complaints	No records of complaints recorded	Use of the laboratory's policy on complaint handling	1%	13%
4.8 Complaints	Complain to management instead of the laboratory	Customer survey form with laboratory's phone no	10%	9%
4.8 Complaints	A customer calls in a complaint that he needs his standard calibrated by tomorrow.	and root cause analysis is performed. Customer complaints are handled in a important and courteous manner.	10%	30%
4.9 Control of Non-conforming Work	Non-conforming work is performed	Procedure for departure from documented policies and procedures	1%	69%
4.9 Control of Non-conforming Work	knowingly not recalling work when necessary	QM section 49 addresses this issue, SAP 21 addresses this issue, Trained staff to follow procedures in QM and	5%	30%
4.9 Non-Conforming Control	Control chart on a check standard weight seems to be drifting out of control.	SAP 17, Error and Non-conforming work procedure would be reviewed. Root cause analysis would be performed. The balance would be check to see if any calibration was needed. The check standard would be checked for any instabilities. The facilities and environment would be checked for any instability.	20%	50%
4.10 Improvement	5-gallon test measures were heavy to lift up to the 36 in high sink during calibration.	The Lab improvement uses a thork lift to carry up the 5-gallon test measures to do the 30 second pour and 10 second drain for calibration.	17%	30%
4.10 Improvement Action	Areas of the laboratory are not evaluated for improvement	Periodic review of different areas of the laboratory for improvement, Periodic review of customer needs	4%	50%
4.10 Improvement Action	Not completing corrective actions identified in audits	Scheduled follow-up meeting as a part of our internal audit schedule to review actions	10%	50%
4.11 Corrective Action	Corrective Action is not done or not complete	Corrective Action Form, Tasks are assigned to personnel to investigate the cause, Due Dates are set to achieve the goals of the corrective action, Corrective Actions are reviewed after implementation to validate the resolution of the corrective action, Measurement	10%	50%
4.11 Corrective Action	Use of outdated publication resulting in outdated SOP calibration being used	Periodic Review of Master List, Assign responsibility for maintaining periodicals/publications , Perform internal audit of publications and storage	25%	40%
4.11 Corrective Action	Corrective actions improperly recorded	Use laboratory policies and procedures for corrective action	8%	13%
4.11 Corrective Action	Power surges in the electrical system in the Lab happen periodically and may harm the balances that are connected to the wall outlets	The Lab used corrrective action and has purchased APC battery back up and surge protectors to protect all balances and computers from electrical surges and power failures.	25%	30%
4.12 Preventive Action	Sources of nonconformities are nor identified.	The policy of the Lab is to use preventive action and identify nonconformities and improvements to prevent sources of nonconformities. Root cause analysis is done to identify the cause of the nonconformity.	18%	30%
4.12 Preventive Action	A piece of equipment vital to laboratory operations is not maintained	Schedule for maintenance of equipment	15%	83%
4.13 Control of Records	The laboratory computer files are destroyed due to a computer hard drive failure	The computer files for the Lab are backed up daily on to a flash drive and copied to all Laboratory computers and laptops.	13%	45%
4.13 Records	Unauthorized access to office, files, computer system	Site security, keypads, door locks, External data back-up procedures (shared server), computer passwords,	20%	80%
4.13 Records	Records not kept in a secure manner	Laboratory procedure on record control	1%	73%
4.13 Records	Records and documents on your computer could be erased or destroyed if your computer doesn't work one day	the lab files are backed up on a flash drive every day at the end of work , The computer lab files are on three separate computer hard drives, lab reports and other documents are printed (hard copy)	10%	70%
4.14 Internal Audits	The laboratory failed to complete an internal audit of its activities	Audits scheduled ahead of time to ensure they are completed	1%	93 %

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4.14 Internal Audits	Facilities audit finds no humidity controls in large volume area	Deviation to requirements authorized after study, No calibration performed during time when outside requirements	25%	10%
4.14 Internal Audits	Internal audits are not done for areas in the quality management system.	The internal audits are scheduled and completed before the NISTannual submission for recognition.	28%	20%
4.14 Internal Audits	Whole host of items are rendered obsolete because not being monitored.	Internal audit performed at a min. of twice a year (more than requirement of once). Employees take turns with different sections of HB 143 to eliminate bias. Split up internal audit into "chunks" to prevent rubber stamping of items in checklist. Have weekly meetings/roundtable to discuss set topics for review.	60%	60%
4.15 Management Reviews	Incomplete management review	Covered in QM section 415, Covered in SAP 18, Trained staff on using QM and SAP's, Peer review,	5%	30%
4.15 Management Reviews	The management review is missing some of the information that should be included in it	A checklist of the items required in the management review	4%	30%
4.15 Management Reviews	During the management review meeting, we failed to discuss and address a failed proficiency test	A check list is used to make sure that all topics are addressed and covered	5%	5%
4.15 Management Reviews	Failure to discuss failed PT during Management Review meeting	Checklist used to insure that all topics are addressed and discussed	5%	5%
4.15 Management Reviews	The management review is missing a few topics for discussion.	The format of the management review has an outline form for all topics for discussion with top management.	8%	30%
4.15 Management Reviews	Old obsolete equipment being used.	Increased management review meetings from once to twice a year. provide very detailed information in review - to solicit upper management of "buy-in". Weekly meetings to discuss/share ideas and comments regarding lab operations. Require all laboratory personnel to attend, as well as bureau director. Maintain a dry erase board - allow all employees to write down ideas for later discussion. Available 365	40%	50%
5.1 General	Laboratory not kept clean	Regular cleaning of the laboratory	6%	35%
5.2 Personnel	New metrologist (or other new staff)	Damage to standards	10%	95%
5.2 Personnel	An employee leaves the laboratory	Plan for replacement of employees	8%	93 %
5.2 Personnel	Retirement of only metrologist	Can hire one year before retirement	90%	76%
5.2 Personnel	Only one metrologist in Lab. The Lab would shut down if the metrologist position were vacant (no metrologist in Lab)	The State policy is that due to budget restaints, management cannot hire another metrologist for the Lab unless the metrologist leaves or the position is vacant. Usualy time to fill the metrologist position is a year or more and three years to get fully trained to open at Echelon III (legal metrology capable).	20%	80%
5.3 Facilities and Accommodations	The Air conditioner in the Lab goes out due to electricity failure	the lab balances are hooked to an APC battery back up, the lab calibration is stopped if the environment is out of HB 143 specifications, the AC is turned back on when the electricity turns on, the environment in the Lab is monitored 24/7 for temp and humidity,	30%	50%
5.3 Facilities and Accommodations	Environmental conditions go out of control in a laboratory room	HVAC system regularly maintained and environmental conditions recorded	18%	50%
5.3 Facilities and Accommodations	Electrical power into the lab fluctuates	Surge protectors on all balances, Control charts to monitor process	60%	15%
5.3 Facilities and Environment	The AC goes off due to electrical failure. Environment goes outside HB 143 guidelines.	[illegible] back up to prevent damages from electric surges. The AC is reset as soon as possible when the electricity is turned on. All calibrations are put on hold until the HB 143 environmental guideline are met for at least 24 hour period.	30%	30%
5.4 Calibration Methods	A calibration method is developed but not validated	Method validation procedure	4%	22%
5.4 Calibration Methods	A new standard come into the Lab and there are no calibration methods stated.	The laboratory will contact the customer to inquire on the use of the standard in the field and the prefered calibration method that should be used.	22%	10%
5.4.6 Measurement Uncertainty	Uncertainty budget missing	Uncertainty budget reviewed and added to method	1%	75%
5.4.6 Measurement Uncertainty	An incorrect standard deviation of the process was used the calculate the uncertainty due to insufficient amount of trial runs.	The uncertainty SOP 29 will be reviewed to see whether any more componets to the uncertainty could be added. The reported uncertainty and the level of confidence (k) would need to be changed and documented on the calibration report. More trial runs using a check standard would need to be done to get a better and reliable s(p) use in the uncertainty.	10%	40%
5.5 Equipment	A balance has been overloaded or a weight dropped on it causing erratic readings	Training on proper handling and use of standards and balances	1%	74%
5.5 Equipment	Balance goes down w/ no backup	annual balance maintenance, staff training on balances before allowed to use	35%	60%
5.5 Equipment	Damaged proving ring due to high humidity level in the lab in a specific day of 2015	Visual inspection (to verify area and degree of rust) , Analysis of results from equipment (to verify if damage caused changes in results)	20%	55%

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5.5 Equipment	Pinching, crushing, falling, slipping, projectiles Trip hazard with cords, boards, and comparators in Large Mass Lab, minor pinch hazards with comparator doors, pinch and crush hazards with standards, slip hazards with wet floor in volume area	Two-person requirement for testing weight carts, Safety and ergonomic training and equipment, PPE, Signage,	9%	40%
5.5 Equipment	The Mettler PK 36 balance is not working properly in calibrating 50 lb weights.	The Lab has purchased a 64 kg mass comparator to replace the old PK 36 balance and will be installed in Sept 2016	25%	50%
5.6 Traceability	Standards calibrated by an outside laboratory with expired standards	Supplier review and checks of standards ran to ensure values	1%	92 %
5.6 Traceability	A calibration laboratory has its reference standards calibrated by another laboratory whose reference standard's calibration is past its documented calibration interval	Set Calibration interval, annual technical audit	5%	90%
5.6 Traceability	Transport and Storage of artifacts	Cases, Training, Gloves/forceps, Clean room, Environmental controls	30%	70%
5.6 Traceability	uncertainties being too large from outside calibration svc	HB 143 guidelines, Mid Map risk assessment training	50%	60%
5.6 Traceability	The Lab receive a calibration for a temperature/ humidity device from a Company the is not traceable to NIST.	check the accreditation and traceability status of all companies that calibrate equipment for the Lab. SAP 11, Purchasing anf Supplier Evaluation procedure would require that the vendor be accredited and traceable to NIST.	11%	30%
5.7 Sampling	Selection of a sample not performed correctly	Use validated procedures for sampling	1%	26%
5.8 Storage and Handling	bad handling of customer standards	notify to the customer of the importance of proper handling of the standards, notify to the customer the impact that will have to his process, give a training of storage and handling of the standards	55%	76%
5.8 Storage and Handling	A customer's artifact goes missing	Inventory tracking procedures and materials used in laboratory	1%	73%
5.8 Storage and Handling	A customer item is lost and your lab is liable for the reimbursement to the company	Chain of custody and procedures to ensure secure handling	5%	70%
5.8 Storage and Handling	Weight could "come loose" in shipment, damaging the weight (or weights)	Pack the weights properly using appropriate materials to restrict their movement	36%	70%
5.8 Storage and Handling	Damage/Contamination	Quality Manual section in handling artifacts	10%	60%
5.8 Storage and Handling	Improper/Poor handling of weights	Handling procedures in QM, SAP 11, Separate forceps labeled for standards and customers weights, Control charts - could show handling mishaps of standards and check standards, Highly polished standards to show any scratches or smudges,	10%	25%
5.8 Storage/ Handling	The Lab receives a weight kit and the weights are all over upside down and mixed up inside the case, because the foam holders were old and damaged.	The lab will review and follow the SAP 4, Handling Calibration and Test Items. The weights in the case will be removed individually and inspected for any damages. The lab will document the as found condition of all the weights and let the customer know of any damages before calibration is done.	7%	50%
5.8 Storage and Handling	Artifacts are damage in receipt to the lab or shipment to the customer.	Laboratory staff are properly trained in the process of safely packing and shipping weights. Customers are informed of proper shipping practices on our laboratory's work request form.	25%	65%
5.9 Measurement Assurance	The working standard was accidently switched with a customer's artifact	The use of a check standards, control chart, and our participation in proficiency tests would flag this	5%	100%
5.9 Measurement Assurance	Working Standard accidentally switched with client's artifact	Use of Check Standards and Control Charts , Participation in Proficiency Tests	20%	76%
5.9 Measurement Assurance	Recalibration of Items	Recall dates, Database of items, Stickers on items, Dates on Certificates,	10%	70%
5.9 Measurement Assurance	Check standard value not logged	Procedure for performing calibrations and checks	1%	49%
5.9 Measurement Assurance	The control charts were not properly updated real time. Standard deviation of the process have small df and k values.	time, so as to obtain a current standard deviation of the process along with the current df and k value. The control charts are updated for all mass and volume calibrations.	12%	45%
5.9 Measurement Assurance	Check standard measurements go out of control.	Check standard measurements are made each time measurements are being performed at its nominal value; or check standard measurements are made even more frequently. All standards are stored in stable, safe locations to prevent damage. Laboratory has a cleaning and maintenance schedule for equipment such as balances and enviromental instruments.	15%	60%
5.10 Reporting (Certificates)	Errors published in report to customer	Double check all entries in report, Use excel to monitor for possible errors	35%	15%
5.10 Reporting (Certificates)	Incorrect procedure referenced on a calibration report	Have separate calibration report templates for different procedures	1%	5%

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5.10 Reporting/ Calibration Reports	The Lab finds an error in the calibration report after the items were returned to the customer.	Error and non-conforming work procedure would be reviewed. The customer would be contacted and a revised and amended calibration report would be issued.	5%	40%
Safety or Security	Security-Unauthorized personnel in the Laboratory damaging standard or balance	Authorized lab personnel identified, Outside of building kept locked, Testing rooms locked, Keys given out to only authorized personnel, The number of authorized personnel kept to a minimum	20%	60%
5.9 Measurement Assurance	Check standard measurements go out of control.	Check standard measurements are made each time measurements are being performed at its nominal value; or check standard measurements are made even more frequently. All standards are stored in stable, safe locations to prevent damage. Laboratory has a cleaning and maintenance schedule for equipment such as balances and enviromental instruments.	15%	60%