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INSIGHTS

ENVIRONMENTAL ISSUES

Kathie Rezek, MT(ASCP), COLA Surveyor

Environmental issues weigh heavily on the minds of just about everyone these days. Should I buy a more fuel-efficient car? Can I get along without a car and utilize public transportation? Ride a bicycle? A scooter? Is it time to replace the windows in my home? Will that suitcase made of recycled plastic *really* hold up to weekly travel? These are all worthy issues, but I wish to discuss the *laboratory* environment.

COLA criteria **MA 6 through 16** address laboratory environmental issues and are often overlooked under the assumption that the temperature and humidity ranges that have always been in place are still applicable. Many times they are; many times they are not. Have you ever found yourself struggling to maintain freezer temperatures within your established range? I'm certain many of you have wondered how to bring the lab's humidity up to the lower end of the range in the dead of winter without running a humidifier and spewing unwanted bacteria into the air. Why do temperatures and humidity matter and how does one establish the appropriate ranges? One lab I visited had established their temperature and humidity ranges to maintain the "comfort level" of the lab staff. While this is a lovely gesture, those ranges were not necessarily appropriate for the instruments and kits in use.

Let's start with **MA 6**, which specifically addresses humidity. Many analyzers and kits must be maintained and operated (used) within a specific humidity range. These ranges can be found in the

operator's manuals and package inserts in the sections for operating specifications and storage conditions. Many analyzers and kits do not list specific humidity requirements, but when they do, the lab should be careful to meet them. To establish the appropriate humidity range (**MA 14**), check all manuals and inserts and establish the widest all-inclusive range possible. Example: Kit A's package insert states that the kit should be stored between 10-90% humidity and the operating manual for analyzer B lists a range of 20-85%. Since both these test systems are used in the same room, establishing the humidity range at 20-85% ensures that the requirements are met for both systems. Use the same process to establish room temperature limits (**MA 9**).

Refrigerator (**MA 7**) and freezer (**MA 8**) temperature ranges must be established and maintained to ensure the integrity of the reagents and specimens stored within them. QC materials and other reagents have a storage range listed on the packaging. It is often in the form of a thermometer showing the minimum and maximum acceptable temperatures. Look at all the products kept in your refrigerators and freezers and establish the widest possible yet all-inclusive range. I have seen labs which store nothing but cold packs in their freezer struggle to maintain a freezer range of -5 to -10 degrees Celsius. When I ask them why the range is so narrow, the answer is generally, "It's always been that way." You can avoid *creating* problems by asking, "Why do we have this range?" and examining the storage requirements of the products and specimens within the unit.

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INSIGHTS



The Laboratory Environment

FROM THE CHAIR There is a lot of talk about the environment these days, and our feature article in this issue focuses on the importance of maintaining a suitable environment in the laboratories where we work. The environmental conditions in the laboratory can be important for optimal performance of the test kits and instruments we use. It is essential to monitor temperature-dependent equipment and to ensure the proper temperature-controlled storage of reagents and samples. The COLA Accreditation Criteria found in Evaluation Grouping MA (Maintenance) address these environmental factors, and this article offers great tips for compliance from a COLA surveyor.

Within your laboratory testing environment, you must have the appropriate quality and quantity of equipment to meet the requirements for the level of services you choose to offer. The *Insight Into QMS* article explores the issues associated with selecting, using, and maintaining all of your laboratory equipment. The right equipment that is properly maintained is essential to provide accurate and reliable test results for patient care.

Verlin K. Janzen, MD, FAAFP
Chair, COLA Board of Directors

ENVIRONMENTAL ISSUES
continued from front cover

Establish incubator (MA 10), Water Bath (MA 11) and Dry Bath (MA 12) temperature ranges by the same process. Incubator ranges are critical to providing the optimal environment for growth of the organisms being sought on the media used for plating as well as the viability of any specimen that may need to be maintained at a specific temperature. Check the package inserts and product data for QC organisms and check your reference lab client manual and/or specific procedures for specimen requirements to determine the acceptable range. Water and Dry Bath temperatures will depend on the utilization of the bath. If they are used to determine the possible presence of cold agglutinins in a CBC specimen, for example, their temperatures must be maintained within the desired range necessary to warm the specimen to body temperature and maintain it at that temperature. Again, the desired range must be set according to that required by the procedure for which the bath is used.

Most temperature-dependent equipment has built-in temperature monitoring that may or may not print as a daily start-up or status log. If the temperature is displayed on an analyzer screen but not printed or otherwise stored within an analyzer data log, the temperature should be recorded on the maintenance log for that analyzer and checked for acceptability before quality control and patient specimens are tested (MA 13).

When documented temperatures do not fall within the appropriately established range, corrective action must be taken and documented (MA 16). This can be written in a comment section of the temperature log or on a separate problem log. Documentation should include the action taken to correct the temperature including, when necessary, moving products to an alternate and appropriate temperature-monitored location and rechecks of the adjusted temperature until it is within range and stable.

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COLA INSIGHTS

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ENVIRONMENTAL ISSUES
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Unacceptable humidity can be more difficult to correct. In sections of the country where cold winter weather often causes the humidity to fall below the established range, perhaps even below a measurable level, labs struggle with corrective action. As long as the instruments and kits with stated humidity ranges do not specifically prohibit testing when the humidity is out of range, and if the daily function checks and quality control have performed acceptably, a notation to that effect should be documented and testing can be reported.

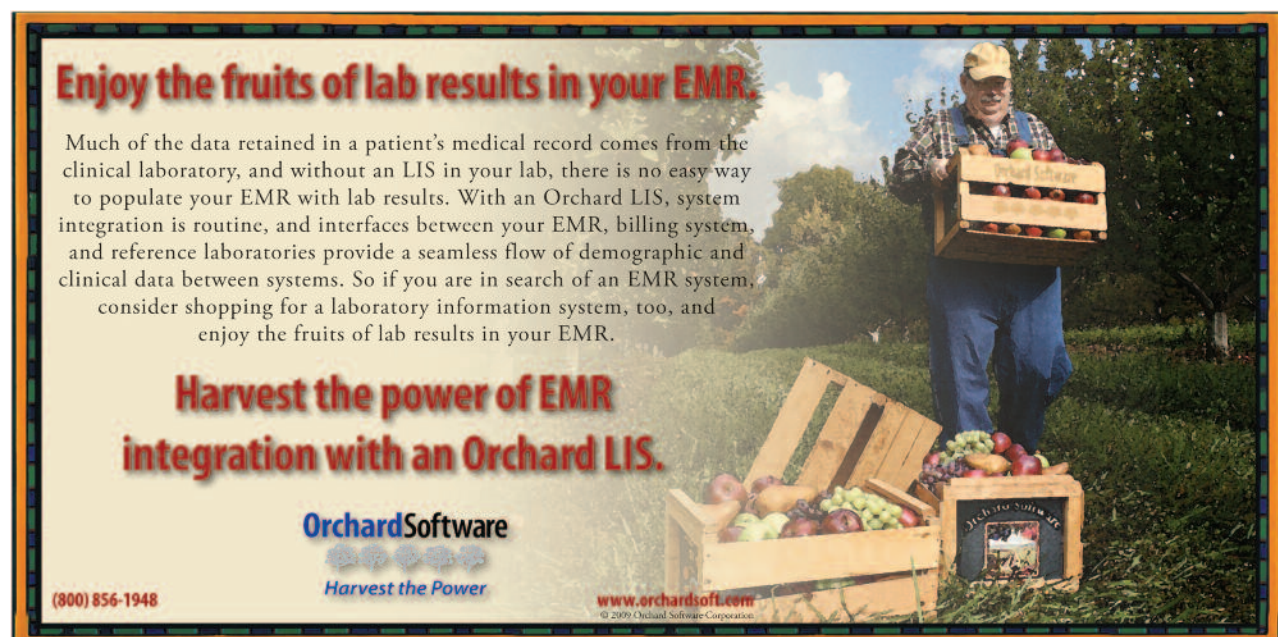
When an analyzer or kit prohibits testing unless the environmental requirements are within the specified ranges, then patient testing must be performed by alternate methods without those restrictions. This may require submitting patient specimens to a reference lab to ensure timely test results for optimum patient care.

Thermometer readings must be verified at least once each year (**MA 15**) by comparing their reading to an NIST thermometer. If the thermometer reading varies from the NIST reading, a correction factor should be applied. For example, when the lab thermometer in Refrigerator A reads 4 degrees Celsius while the NIST thermometer reads 5 degrees Celsius, a correction factor of +1 is applied to the lab thermometer in refrigerator A so that the correct temperature of the refrigerator will be monitored and documented.

When the variation of a thermometer is consistently greater than + or - 2 degrees, a new thermometer should be acquired. When the lab uses NIST-certified and sealed thermometers that do not need calibration checks, the certification documentation that came with each thermometer must be maintained. These thermometers should be carefully examined on a routine basis to ensure that the seal is intact and the integrity of the thermometer has not been compromised. When the seal is broken, the thermometer must be calibrated annually or replaced.

Reviewing the established environmental ranges in labs sometimes reminds me of the story about the family who always cut 4-6 inches off the end of a ham before baking it because each successive generation had done it that way. An investigation back through time revealed that the custom began because great-great-great-grandma did not have a pan large enough to bake the entire ham at once! If you find yourself struggling to maintain a fairly narrow temperature or humidity range, step one is to review that range and ensure it is appropriate for your lab.

Now that you've finished reading this article, why not pull out a quality assessment form and check those environmental ranges?



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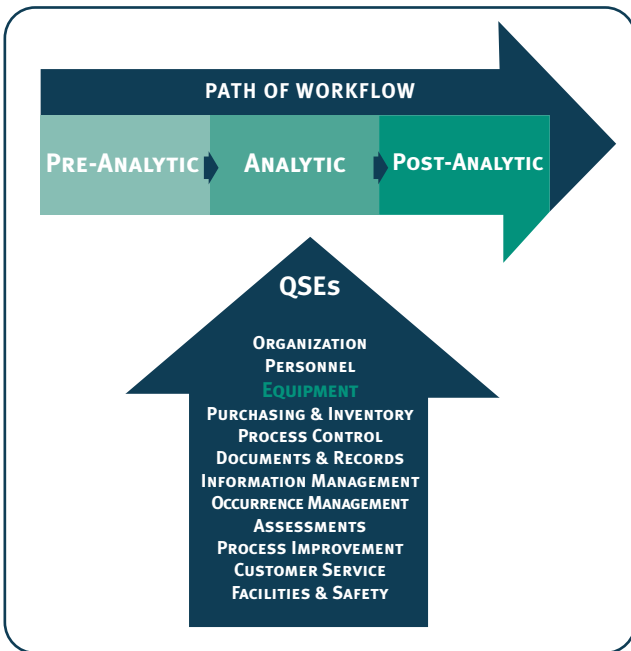
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INSIGHT INTO QMS

QSE: Equipment

Quality Management Systems (QMS) is a systematic approach to quality management with a focus on error prevention and efficiency. The goal is to take quality and effectiveness to a higher level of performance. The Quality System Essentials (QSEs) work together to comprise a quality management system, supporting the path of workflow and forming the foundation of the laboratory's operations.



Without the right equipment that is accurate and reliable, your laboratory cannot provide test results that contribute meaningfully to patient care. **QSE: Equipment** is about taking the time to properly select the right equipment; install the equipment and validate its function; maintain and calibrate the equipment according to established requirements; solve and document equipment-related problems; and maintain all required records.

Your lab needs to have all the appropriate equipment to provide the level of services you offer. This includes equipment used in all the laboratory's technical operations in the path of workflow, such as:

- Analyzers for performing testing
- Measuring instruments
- Temperature regulating devices

There are key considerations when selecting laboratory equipment. Your processes for equipment selection and acquisition should take into account the use of energy, the impact on the environment, and future disposal.

Use the following list to evaluate the functional requirements for each piece of equipment. This will aid in your selection before purchase:

- Load-bearing capacity of the surface on which the equipment will rest
- Space requirements as specified by the manufacturer (known also as the "footprint")
- Electrical requirements
- Ventilation and air quality
- Humidity
- Temperature
- Water type and quality
- Potential hazards
- Other manufacturer requirements

You need maintenance and calibration programs for your laboratory's equipment and instruments. Develop your program from the manufacturer's instructions and applicable accreditation requirements, and be sure to include:

- Schedule of activities to perform
- Instructions for performing each activity
- Records of the results of activities and who performed them, and of any corrective actions and follow-up

For details about this QSE and Quality Management Systems (QMS), see the LabUniversity® QMS courses available from the COLA Store at www.cola.org.

FDA Issues Public Health Notification on Glucose Monitoring Technology

On August 13, 2009, the U.S. Food and Drug Administration (FDA) advised health care practitioners and patients against using glucose monitoring technology that employs a specific test strip when the patients are also receiving therapeutic products containing non-glucose sugars (maltose, galactose and xylose).

The test strips in question contain glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ). This chemical reacts with the non-glucose sugars contained in some therapeutic products to give falsely elevated glucose results. The therapeutic products, such as peritoneal dialysis solutions and certain immunoglobulins, are mainly used for patients with serious medical conditions, including kidney failure and moderate to severe rheumatoid arthritis or those who have recently had surgery. The products should be labeled to indicate the possible interference with GDH-PQQ glucose monitoring devices. Administering an incorrect insulin dosage based on the elevated glucose result could lead to abnormally low blood sugar (hypoglycemia), coma or death. In addition, if your patient's blood glucose is actually low, it could go unrecognized and untreated because the falsely elevated glucose level could be within the normal range. Therefore, if a patient is receiving an interfering product, a laboratory assay that does not utilize GDH-PQQ should be used to measure the patient's glucose level.

In a Public Health Notification and an accompanying Advice for Patients, the FDA listed the manufacturers and brands of glucose test strips that contain GDH-PQQ. The FDA also makes recommendations to minimize the risk of potential shortages of these products until health care facilities can obtain non-GDH-PQQ strips and meters.

For more information, see the following links:

FDA Public Health Notification: Potentially Fatal Errors with GDH-PQQ Glucose Monitoring Technology

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm>

FDA Advice for Patients: Serious Errors with Certain Blood Glucose Meters and Strips

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>

Drug products or therapies with non-glucose sugars

- Extraneal (icodextrin) peritoneal dialysis solution
- Some immunoglobulins: Octagam 5%, Gamimune N 5% **, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human) and HepaGamB
- Orencia (abatacept)
- Adept adhesion reduction solution (4% icodextrin)
- BEXXAR radioimmunotherapy agent
- Any product that contains, or the body breaks down into, the sugars maltose, galactose or xylose

** Within the U.S., Gamimune N 5% has not been manufactured since December 2005, and no lots are in distribution in the U.S.

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Certification Unity

The American Society for Clinical Pathology (ASCP) Board of Registry (BOR) and the National Credentialing Agency for Laboratory Personnel (NCA) have signed an agreement forming a single certification agency for medical laboratory professionals. Although the agreement was signed on July 21, 2009, it does not become effective until October 23, 2009. At that time, the new certification agency, to be known as the ASCP Board of Certification (BOC), will replace the BOR and, according to its bylaws, the NCA will be dissolved as a corporation.

The BOC will operate with complete autonomy from all parent organizations, as required for continued accreditation by the American National Standard Institute (ANSI). This involves all decisions made by the BOC, all BOC programs, all certification related finances and all credentialing related activities.

All individuals with current and active credentials will be transferred to the new BOC. No examination will be required. Those certified by ASCP prior to January 1, 2004, who have not enrolled in the Certification Maintenance Program (CMP), will continue with the

MT(ASCP) credential. Those certified by ASCP after January 1, 2004, who were required to enroll in the CMP, will receive a new credential: Medical Laboratory Scientist or MLS(ASCP). MT(ASCP) credentials will be transferred to MLS(ASCP) credentials as recertification requirements are met through CMP. Individuals certified as Clinical Laboratory Scientists, CLS(NCA), who have maintained active certification (i.e. they have maintained certification through continuing education or reexamination) will receive the new MLS(ASCP) credential.

Similarly, individuals certified as Medical Laboratory Technicians, MLT(ASCP), and Clinical Laboratory Technicians, CLT(NCA), will be unified as Medical Laboratory Technicians, MLT(ASCP). Categorical and specialist certifications will also be transferred to the BOC.

E. Blair Holladay, PhD, SCT(ASCP), Executive Director of the ASCP Board of Registry stated, "This process to achieve a single certification agency took four years and involved many hours of negotiation, consideration of many different models, careful deliberation and due diligence, and a determination to make this work for the profession."

Continued on page 7

SPECIAL

New LabU Discount Offer!

We are all looking for ways to make our dollars go further, and in this issue, COLA will be offering a discount on a selected LabUniversity® on-line course. For September/October we are offering a 30% discount on:

QSE: Equipment

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You can purchase **QSE: Equipment** from the COLA Store at www.colaprof.org. At checkout enter the discount code: **EQ30** to receive the discount. This discount code is valid for purchasing the **QSE: Equipment** course until **October 31, 2009**. (You don't need to take the course by that date, just purchase by that date.)



Look for other discounted courses in upcoming issues of Insights. We want to help keep continuing education affordable for labs!

CERTIFICATION UNITY
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Sheila O'Neal, Executive Director of NCA said that much of the negotiation process work focused on creating a newly reorganized board structure and composition and on resolving variances in policies between the two organizations. "None of that could be announced before now because we have been busy coming to agreement. Now we will roll up our sleeves and start the operational work."

Members of both organizations will sit on the Board of Governors for the new BOC. The complete composition of the Board of Governors is as follows: five ASCP Fellows (pathologists), five ASCP laboratory professionals, four representatives nominated by ASCLS, two representatives nominated by the Association of Genetic Technologists (AGT), eight representatives nominated by the eight participating societies (one each) and one public representative.

The participating societies are AABB, the American Association for Clinical Chemistry, the American Association of Pathologists' Assistants, the American College of Microbiology, the American Society for Cytopathology, the American Society of Hematology, the Clinical Laboratory Management Association and the National Society for Histotechnology. The public representative will be nominated by ASCP, ASCLS, AGT, the participating societies and the members of the Board.

The unification of the ASCP BOR and the NCA will provide benefits to students and educational programs, employers, professionals and the public. The BOC will be an agency committed to peer credentialing, that will be responsive to the needs of the profession.

More information and answers to Frequently Asked Questions can be found at www.ascp.org/bor and www.nca-info.org.

References:

Single Certification Means Good-bye to Med Techs (MTs) and Clinical Lab Scientists (CLSs)!

DARK Daily Laboratory and Pathology News
<http://www.darkdaily.com/single-certification-means-good-bye-to-med-techs-mts-and-clinical-lab-scientists-cls>

ASCP BOR and NCA Form Single Certification Agency

<http://www.ascp.org/FunctionalNavigation/certification/ASCP-BOR-and-NCA-Form-Single-Certification-Agency.aspx>

ASCP BOR and NCA Form Single Certification Agency

<http://www.nca-info.org/documents/SingleCertificationAgencyNews-July09.pdf>
<http://www.nca-info.org/documents/BORNCAUnificationSlides7-24.pdf>



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