NCBA NEWS

April 2017 Volume 36, Issue 2

In This Issue

Contact Us: bodall@ncbiomedassoc.com

Keeping Up with the Joint Commission

Published on December 10, 2016

By Chris Hayhurst

Many in the HTM community had questions about changes to JC standards slated for 2017. So we asked around for clarification.

If you were among those at AAMI's 2016 conference, chances are you made special arrangements to stay through the last day. On Monday June 6, at 8:30 am, George Mills, MBA, FASHE, CEM, CHFM, CHSP, director of the Joint Commission's (JC's) Department of Engineering, was scheduled to speak in Ballroom B of the Tampa Convention Center.

Mills' presentation—"The Joint Commission Update"—would go over what HTM departments needed to know about upcoming changes to JC standards. Anyone who worked in a JC-accredited facility, and who knew what it was like to endure an inspection survey, would want to be there to hear what he had to say. To miss Mills' talk was all but unthinkable.

One clinical engineer who was in attendance was Matthew Baretich, PE, PhD, president of

Baretich Engineering in Fort Collins, Colo. In his work, Baretich visits hospitals around the country to assess their HTM programs and identify opportunities for improvement. Helping those facilities prepare for inspection surveys is often part of the job—meaning he needs to know the latest JC standards—which, Mills reminded his audience, go into effect in January.

“Almost all of the changes are pretty straightforward,” Baretich says. “They’re really just focused on cleaning things up.” Some old requirements that were no longer deemed necessary were removed, he says, while others were edited for clarification.

“It was mostly basic housekeeping stuff—and making sure that their standards line up with those of CMS.” (Alignment with the Centers for Medicare and Medicaid Services is an issue because many organizations rely on the JC’s “deemed status” surveys to certify they’ve met the agency’s health and safety stipulations, and therefore qualify to participate in its programs. The JC can offer these inspections only because CMS has determined its standards meet or exceed its own requirements.)

Still, Baretich says, there were a few items in Mills’ talk (and which later were included in JC’s “prepublication standards”—a kind of rough draft that may be altered slightly before the official publication goes to print) that struck him and others as “very concerning.” Here’s a quick rundown on those pending changes, what they may mean for JC-accredited facilities, and some clarification from George Mills himself.

New Scoring Methodology

One notable post-survey process change is the JC’s transition to using the “Survey Analysis for Evaluating Risk” (SAFER) scoring methodology to document and communicate to an organization the severity of its findings, notes Clarice M. L. Holden, BSE, supervisory biomedical engineer with VA Greater Los Angeles Healthcare System. The new scoring method is “fundamentally different” than the previously used “Criticality Method,” she says, and appears to have both advantages and disadvantages.

On the plus side, the SAFER matrix allows for greater specificity for describing findings, “which will be a boon for hospitals in need of determining what their priorities should be.” On the other hand, Holden notes, the new methodology also appears to leave the severity of findings “open to interpretation of the surveyor—which could be problematic if surveyors are not consistent in their analyses.”

Time to REFRESH

Beyond the adjustment to scoring methodology, the majority of changes for 2017 are a result of “Project REFRESH,” a JC initiative to simplify, modernize, and streamline their requirements. Project REFRESH has led to the deletion of 225 “Elements of Performance,” or EPs. A majority of those deletions took place in 2016, while the rest (94) will take effect this January.

While as Baretich pointed out, most of those deletions amount to simple “housekeeping,” one in particular has raised red flags in the HTM community. EC.02.04.01, EP 1 required hospitals to solicit input “from individuals who operate and service equipment when it selects and acquires medical equipment.” The JC has indicated that it’s eliminating this EP because it addresses a “routine part of operations of clinical-care processes,” and

"organizations already have multidisciplinary teams in place to give input on equipment."

But Holden, for her part, says that is a mistake. "Requiring biomedical engineering to be part of the process was a way to ensure proper implementation plans would be in place, and that equipment expertise would be available to administrators making the purchasing decisions," Holden says.

She has personally witnessed what can happen when a requestor of equipment doesn't consult with biomed prior to purchasing, she adds. "Things like incomplete orders, where they bought a medical device system but not the server to manage its applications—or buying equipment with no implementation plan," which in turn led to compatibility issues. The result in each instance: "Additional costs and delayed implementation of the systems," Holden says.

Changes to EC.02.04.01, EP 4 and EC.02.04.03, EP 3

Most will agree that the biggest changes announced by the JC are within EC.02.04.01 (related to management of medical equipment risks) and EC.02.04.03 (related to inspections, tests, and maintenance of medical equipment). Both entries appear in October's prepublication standards, but EC.02.04.01, EP 4 has since been revised.

EC.02.04.01, EP 4 now states:

The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

EC.02.04.01, EP 4 also includes three separate notes:

Note 1: *The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice, such as the American National Standards Institute/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.*

Note 2: *Medical equipment with activities and associated frequencies in accordance with manufacturers' recommendations must have a 100% completion rate.*

Note 3: *Scheduled maintenance activities for high-risk medical equipment in an AEM program inventory must have a 100% completion rate. Scheduled maintenance activities for non-high-risk medical equipment in an AEM program inventory are to be completed at 100%. AEM frequency is determined by the hospital AEM program.*

EC.02.04.03, EP 3 now states:

The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.

Note: *Scheduled maintenance activities for non-high-risk medical equipment in an AEM program inventory are to be completed at 100%. AEM frequency is determined by the hospital's AEM program.*

Stephen Grimes, FACCE, FHIMSS, FAIMBE, managing partner and principal consultant with Swampscott, Mass.-based Strategic Healthcare Technology Associates, says he's happy to see reference to AAMI in the standards, as it recognizes the work of the association's Medical Equipment Management Committee (which he, George Mills, and others are on). The sticking point, he says, is "that a 100% completion rate is going to be problematic."

Most hospitals, he notes, "still haven't developed a good AEM program," opting instead to follow manufacturers' recommendations. "And that's what they'll tell you, but if you ask them to document or verify that they're doing everything the OEM requires all of the time, virtually none of them can," Grimes says.

Very few hospitals maintain records of OEM maintenance requirements—instead relying on generic maintenance procedures for equipment categories. And typically hospitals target 90% to 95% completion rates for scheduled maintenance on non-critical/non-high-risk equipment, Grimes says. "But achieving 100% completion rates on all scheduled maintenance? That's practically impossible."

It's one thing to require 100% completion on equipment that is considered to be "high-risk," Grimes says. Those items (including devices such as pacemakers, defibrillators, anesthesia machines, and ventilators) comprise roughly 5% of a hospital's inventory, "so they're a very small subset of what you're responsible for overall." To do the same for "non-high risk" equipment like sphygmomanometers and vital-signs monitors, Grimes says, is asking too much.

"It's going to put a burden on healthcare organizations that most will find extremely difficult to handle."

Matthew Baretich agrees. "I may be overthinking this, or maybe I'm not understanding the new requirements correctly, but I think most facilities can expect a surprising expansion of their workload in 2017," he says. Current standards call for 100% on-schedule completion of scheduled maintenance only for high-risk medical equipment. The revised standard, however, appears to call for the 100% target even for non-high-risk medical equipment if it is not in an AEM program, Baretich explains.

"With the high-risk equipment, most HTM departments are really good about being thorough and working hard to find every last device," he says. "But for non-high-risk medical equipment, it had been OK if you could just hit 90%" of that equipment, Baretich notes. "Getting that last 10% is going to be tough."

Recommendations

The obvious solution for most facilities will be to develop an AEM program, Baretich says. "Most have been slow to do so because of the overhead and the ongoing monitoring that's required, and a lot of them just don't know where to begin. They're looking for consensus on how move forward."

While that consensus may take some time to develop, one HTM leader does have a few suggestions. Following our request for clarification on standards that appeared to differ from those he noted in his AAMI presentation, George Mills responded in part with the following: The Joint Commission, Mills writes, "has supported alternative equipment

management programs, provided the alternative equipment management decisions are made by a qualified individual using written criteria."

There are no prohibitions against applying an AEM strategy to high-risk devices, Mills notes, but there are certain restrictions related to federal or state law; imaging and radiologic equipment; medical-device lasers; and new medical equipment.

Equipment that has not been evaluated according to the written criteria of an organization's AEM must follow manufacturers' recommendations at 100% compliance, he says. "An advantage to the AEM is the flexibility in managing equipment activities and frequencies. But without the structure of the AEM, alternatives to equipment management are not defensible."

The new EP language, Mills says, gives an organization "full control of the activities and frequencies" in an AEM program. "The requirement is for completing 100% of the activities identified by the organization in a frequency also identified by the organization," he adds.

Mills offers the following example of an acceptable AEM program:

Scheduled Maintenance Activity: Changing Oil in a Pump

The manufacturer's recommendations are:

Maintenance Activity:

1. Turn off the pump
2. Remove the oil plug.
3. Drain the used oil.
4. Remove the oil filter.
5. Wipe the filter seal.
6. Install a new filter.
7. Replace the oil plug.
8. Refill crankcase with the new oil.
9. Check the oil level.

Activity Frequency: Monthly

The AEM program has determined (after oil analysis performed over several months) that changing the oil can be extended to every other month, and that replacing the oil filter can be extended to semi-annually. The organization has set its frequency policy for bi-monthly as every other month +/- 10 days; and semi-annual as every six months +/- 20 days.

Adjusted activities, pump maintenance, Cycle 1 (does not include filter change):

1. Turn off the pump.
2. Remove the oil plug.
3. Drain the used oil.
4. Replace the oil plug.
5. Refill crankcase with new the oil.
6. Check the oil level.

Frequency: Bi-Monthly*

Adjusted activities, pump maintenance, Cycle 2 (includes filter change):

1. Turn off the pump.
2. Remove the oil plug.
3. Drain the used oil.
4. Remove the oil filter.
5. Wipe the filter seal.
6. Install the new filter.
7. Replace the oil plug.
8. Refill crankcase with the new oil.
9. Check the oil level.

Frequency: Semi-annual*

**It is acceptable to combine the oil change and the filter change simultaneously* during *semi-annual activity.*

"When evaluating the program," Mills writes, "the surveyor would ask what activities were scheduled and [whether] were they done at 100% completion rates…Less than 100% completed activity will result in pump failure." Next, he says, "the surveyor would ask what frequencies were established and [whether] they were done as per the organization policy."

Organizations, Mills recommends, should establish policies with frequencies "that can be accommodated" and which do "not place the equipment at risk."

Time Will Tell

Implementing a strong AEM program will of course require time and energy of HTM departments, and will likely entail ongoing consultation with experts in the industry, including JC surveyors. The good news, Stephen Grimes says, is that the JC's "typical MO" when they come up with new standards "is they don't hold people accountable right away."

Instead, he says, surveyors usually ask questions before they start enforcing, "to educate themselves as well as those they're surveying." Nevertheless, Grimes says, he has a prediction: "I suspect we'll hear a lot of concern from people as this sinks in."

Chris Hayhurst is a contributing writer for 24×7*. For more information, contact chief editor Keri Forsythe-Stephens at kstephens@allied360.com.* This is a reprint!!!

NCBA Facebook Page. Follow us by

Clicking Here

Go to the NCBA Website to check out our Scholarships

Click Here

2016 Vendor List

We are looking forward for another great year 2017

Pacific Medical	Replacement Parts Industries (RPI)	Maull Biomedical Training, LLC
Technical Prospects	Crothall Clinical Equipment Services	Rieter Medical Services
SONODEPOT INC	Pronk Technologies	ISS Solutions
Sage Services Group	First Call Parts	Amico Accessories
TUV Rheinland	Cadmet, Inc.	USOC Medical
MedEquip Biomedical	Physio-Control, Inc.	Zoll Medical Corporation
Global Medical Imaging, LLC (GMI)	Medtronic	Tri-Imaging Solutions
GeoSonics, Inc	Ed Sloan & Assoc.	GE Healthcare
Systems Electronics, Inc.	Blue Ridge X-Ray	GE Healthcare
Network Imaging Systems	PartsSource, Inc.	ReMedPar
Spectrum Technologies, Inc	Summit Imaging	Exclusive Medical Solutions
MediMizer, Inc	Nuvolo Technologies	Anacom Medtek
Mindray	The InterMed Group	International Medical Equipment and Service (IMES)
IMS	Denova Medical, Inc	Northfield Instrument Services
Transtate Equipment Company	Advanced Electronic Services, Inc	Philips Healthcare
US Medical Systems	MEDiSURG	ATOM Medical
Interstate All Battery Center	GCX Corporation	Hill-Rom Services, Inc.
AMX Solutions, Inc. (Formerly Digital MXS, Inc.)	ERBE USA	Welch Allyn, Inc.
Southeast Laser Systems, Inc.	Spacelabs Healthcare	Baxter Healthcare
Fukuda Denshi	Metropolitan Medical Services of NC, Inc.	Bayer Healthcare
Bio-medical Equipment Service Company	Enthermics	Sodexo
Varian Medical Systems	Gopher Medical	AllParts Medical, LLC
EQ2	Absolute Imaging Solutions	RSTI
Rigel Medical	Southeastern Biomedical Associates, Inc.	Ironshore Insurance
Elite Biomedical Services	Fluke Biomedical	MD Publishing, Inc.
BC Group International, Inc.	RepairMED	Wellness Robotronic Industries
ATS Laboratories, Inc.	Tekyard Medical	24x7 Magazine
Draeger	Advanced Sterilization Products	AAMI
American I.V. Products, Inc.	Masimo	DOTmed
A+ Medical Company, Inc.	MW Imaging	

Stand-alone Classes being offered by NCBA are:

CBET Certification Review

Class Dates 4/4/2017 through 4/7/2017

Clink in the link below to register

NCBA CBET Class Registration

Held in Mooresville, NC

Cost $350.00

&

Introduction to Cardiovascular Imaging Services

Class Dates 5/2/2017 through 5/17/2017

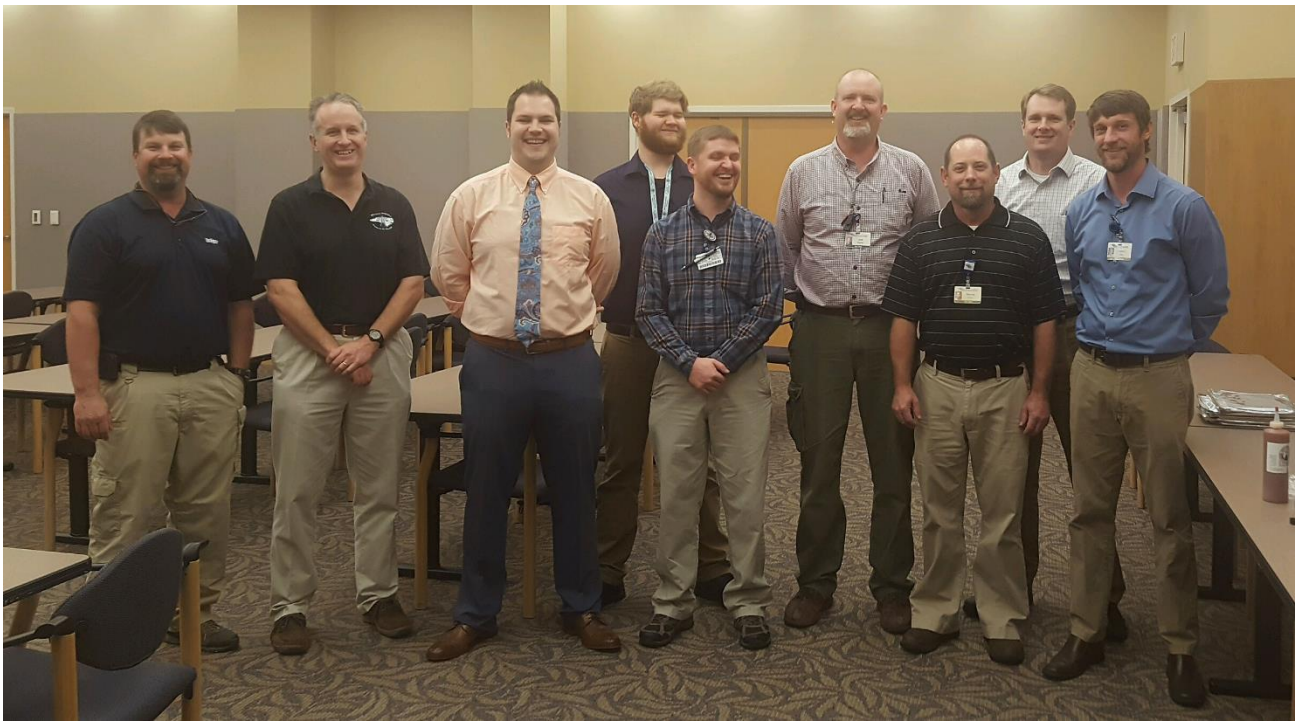
Philips Allura FD Series 5/2-5/3

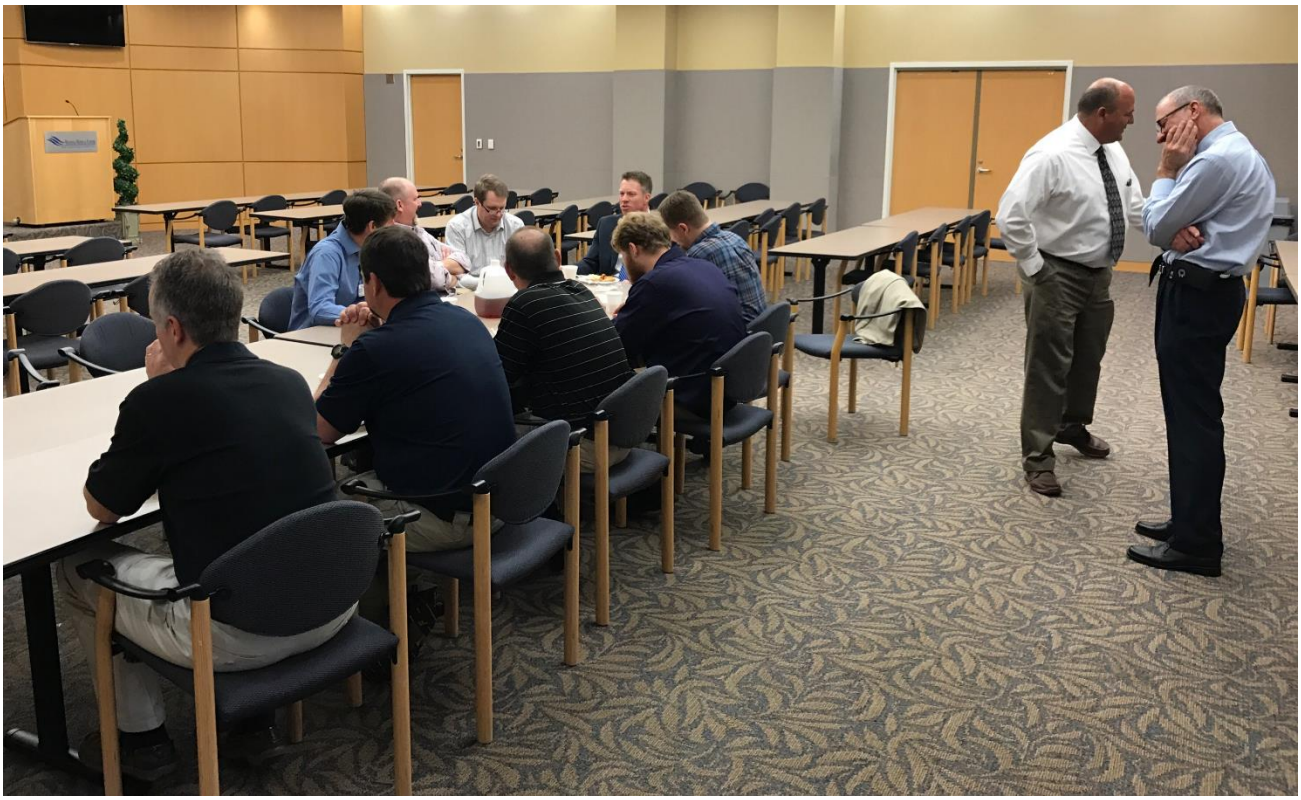
Siemens Axiom Artis & Zee 5/9-5/10

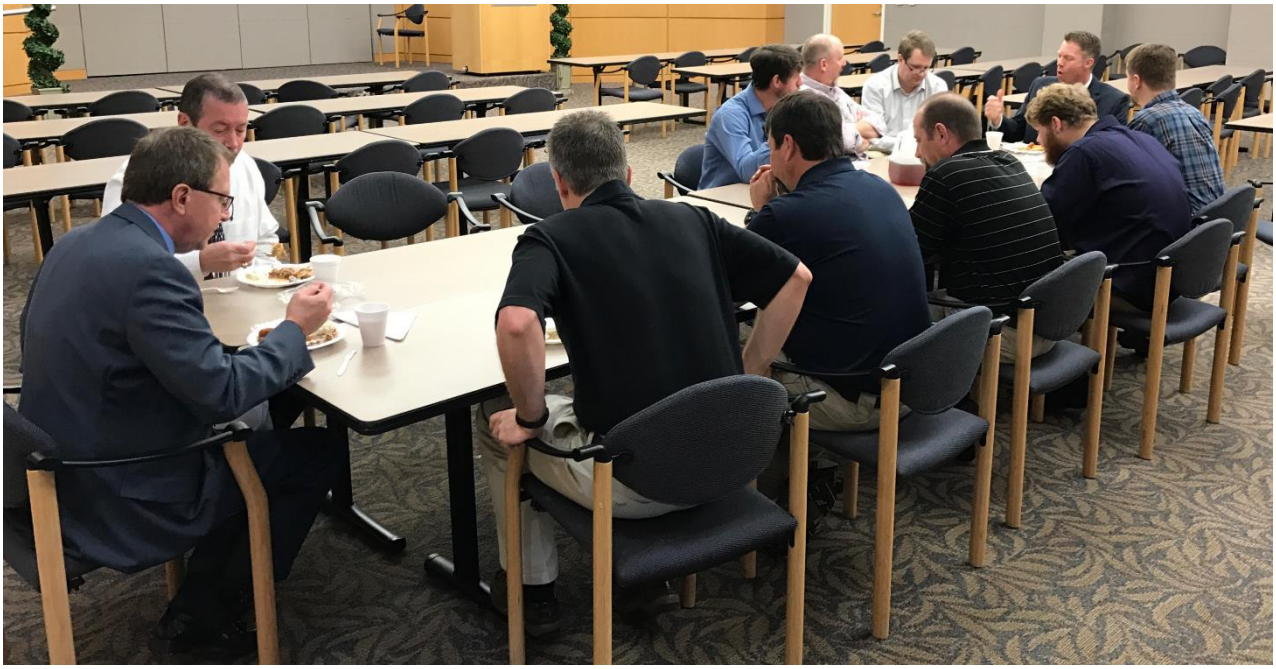
GE Innova Series 5/16-5/17

NCBA Imaging Classes Registration

NCBA Board of Directors provided lunch on March 28th, 2017 to the winners of The Shop of the Year: Appalachian Regional Health System!







SOUTHEASTERN
BIOMEDICAL ASSOCIATES INC

4360 Hickory Blvd. • Granite Falls, NC 28630
828-396-6010 • Fax: 828-396-6030
888-310-7322
info@sebiomedical.com
www.sebiomedical.com

On-Site Test Equipment Calibration

"Biomeds helping Biomeds"

Southeastern Biomedical is committed to providing convenient, cost effective on-site calibration and repair service of test, measurement, and diagnostic equipment operated by biomed departments in hospitals.

Our on-site test equipment calibration service will:

- Eliminate shipping costs and shipping damage
- Reduce downtime from weeks to hours
- Increase productivity

Our new high-end test devices provide us with a wide range of capabilities allowing us to:

- Calibrate and repair a wide variety of manufacturer's test equipment

Our calibration management software will:

- Allow us to identify and notify you when your equipment is due for calibration
- Provide a history of calibration and repair services performed on your test equipment

All calibrations are traceable to the National Institute of Standards and Technology (N.I.S.T.)

www.sebiomedical.com

THE NCBA WANTS YOU!!!

Every year at the annual symposium 6 board members are elected for a 2 year term. The board needs individuals who want to continue to further the education and improve the lives of the Biomed. As well as, continue the growth of the NCBA as an organization. To serve your biomedical society as a volunteer board member is rewarding in so many ways. I have served on the NCBA Board for a 2 year term and currently in my second 2 year term. I will rotate off in 2018. It has been a true honor and privilege to serve alongside the other board members, as we plan the symposium, standalone classes, and the board retreat to mention only a few things. If you would like to join this outstanding group of individuals, please send an email to record@ncbiomedassoc.com with your name and contact information. Thank you and we look forward to serving with you.

Board of Directors

The NCBA board of directors welcomes any comments or suggestions you may have in order that we keep improving the NCBA. Below are the current members of the board who are here to serve you.

President	Codi Nelson, CBET	pres@ncbiomedassoc.com
Vice President	Robert Duvall, CRES	vp@ncbiomedassoc.com
Treasurer	Sally Goebel	treas@ncbiomedassoc.com
Membership Secretary	Jeremy Collins	memb@ncbiomedassoc.com
Recording Secretary	Terry Morris	record@ncbiomedassoc.com
Ex-Officio	Glenn Scales, CBET	exofficio@ncbiomedassoc.com
Board Member (1)	Clint McCoy, CBET	bod1@ncbiomedassoc.com
Board Member (2)	Thomas Bresnahan, CBET	bod2@ncbiomedassoc.com
Board Member (3)	Daniel Norman, CBET	bod3@ncbiomedassoc.com
Board Member (4)	Boyd Campbell, CBET, CRES	bod4@ncbiomedassoc.com
Board Member (5)	Susan Trombley, CBET	bod5@ncbiomedassoc.com
Board Member (6)	John Noblitt, CBET	bod6@ncbiomedassoc.com
Board Member (7)	Biran Lefler, CBET	bod7@ncbiomedassoc.com