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Calibrate

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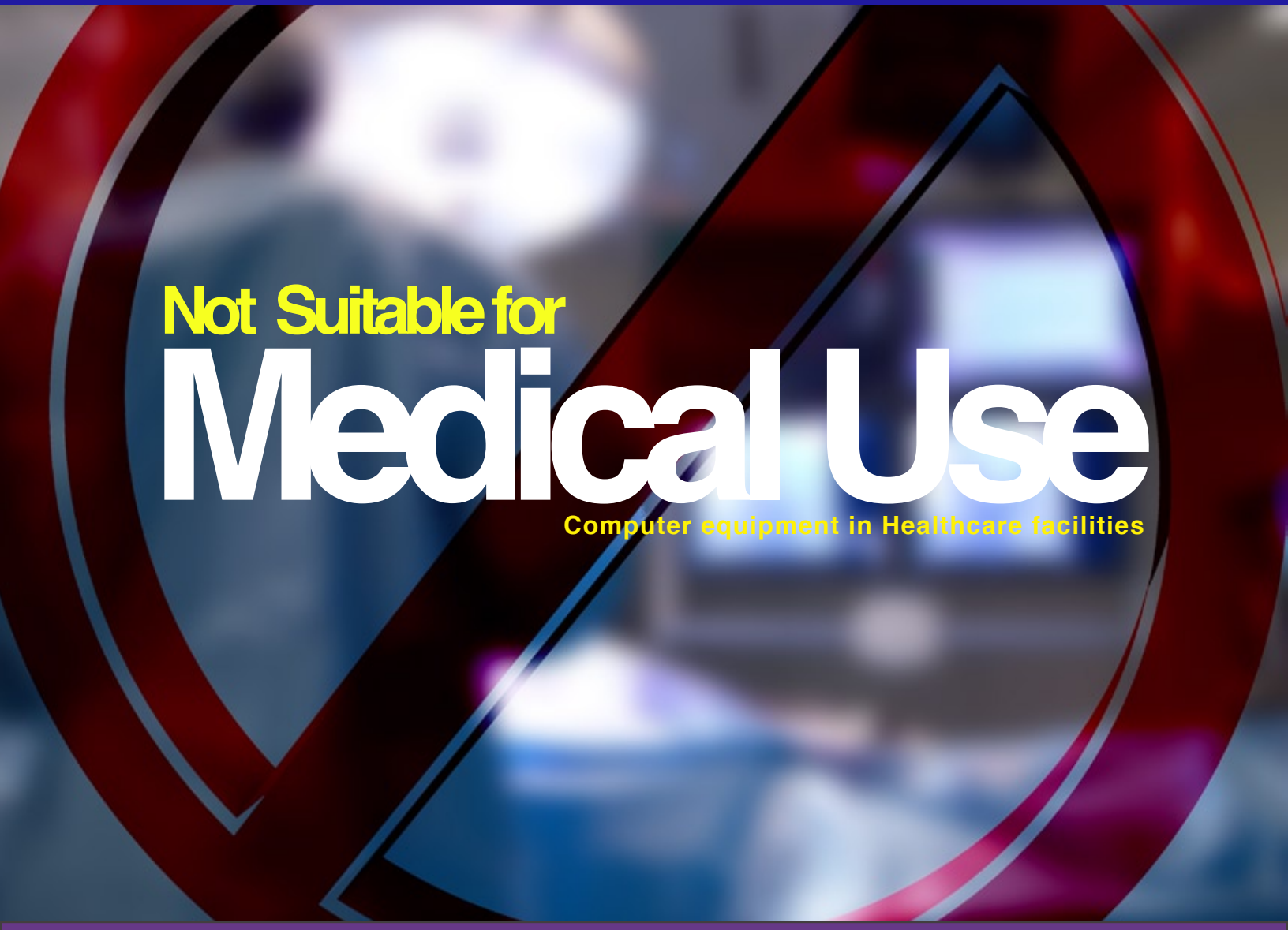

Not Suitable for Medical Use

Computer equipment in Healthcare facilities

The 31st annual Symposium of the North Carolina Biomedical Association.

Your Contributions Please !

If you think you can author an article related to Biomed-Medicine (doesn't matter what exactly, we are extremely receptive to new ideas) please email us at : editor2@ncbiomedassoc.com

For the Biomed in you

Calibrate
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Sam Collins

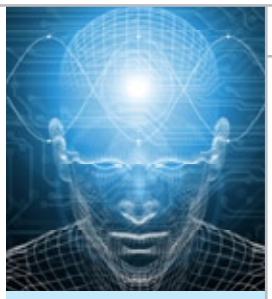
Dear friends,

Thanks so much for your great feedback after the first issue of the new NCBA magazine Calibrate was released three weeks ago. We are going to be putting a few issues out rather quickly because we have a little catching up to do and our 31st NCBA Symposium is fast approaching. For the latest updates on breaking news in the NCBA check the website regularly. Our new Webmaster, Jeremy Collins, is hard at work keeping us up to date. You can see, right on the home page, updates on the website are listed to help you know when new information is available.
I have received articles from members and would like to say "Thanks" for your support. Keep those articles coming, you are our best source of information. If you would like to see an article about a certain topic please feel free to let me know as well. We want to know what you are interested in. You can help us make "Calibrate" a resource you will look forward to reading and hopefully one you will want to advertise in as well.
After the symposium this December Calibrate will be published six times per year and will be made available for download and email distribution around the middle of January, March, May, July, September and November. All members are encouraged to send items of interest to the Newsletter Editor at e-mail address editor2@ncbiomedassoc.com for inclusion in "Calibrate".

Sam S. Collins
Editor, Calibrate

Click here for more information

By Greg Smith, NCE (Certified product safety Engineer)



Not Suitable for Medical use

Can computer equipment in hospitals kill patients? Product Safety and Biomedical Engineering experts know the answer is "Yes", so do designers and manufacturers of Safety-certified medical equipment. Why would an organization like ASHE (American Society for Healthcare Engineering) attempt to potentially cripple US Safety Standards and pressure the Joint Commission to have this testing stopped?. At the same time, when it comes to the subject of inspection of equipment for US certification and enforcement of existing laws, ASHE is silent. Why are ASHE and the Joint Commission not aggressively encouraging the proper testing and deployment of computer equipment in hospitals under existing regulations and safety standards?

The following is a quote from a letter written in February 2009 by ASHE to the Joint Commission: "This is a rather timely subject as ASHE is working hard to debunk a lot of legend behind leakage current and with it remove it from NFPA 99.… Our proposal has passed the public comment stage and has been accepted by the technical committee. So we anticipate a significant reduction in requirements for the 2010 NFPA 99 and hope for elimination in the 2013 edition". Clearly, this shows ASHE's intention to reduce the current level of safety currently in place. It's important to consider that ASHE has no product safety professionals in their "working groups".

The JCAHO (Joint Commission on Accreditation of Healthcare Organizations), has also never taken a firm position on certification and testing of medical equipment, instead, relying on each organization to police themselves and attempt to identify safety-certified equipment. A search of the JCAHO website (www.jointcommission.org) reveals that there are no references to safety of electrical equipment, UL Standards, certification of Listed equipment, or leakage current. Also, there is no mention of 29CFR 1910 Subpart S, which requires all equipment in the workplace to be Listed or Labeled by an NRTL (Nationally Recognized Testing Laboratory). The term "Listed equipment," means that equipment is certified by a US NRTL, including the use of applicable Standards, in this case UL 60601.

What is Leakage Current and how does it directly affect the human body? If a piece of equipment is designed with improper grounding or compromised ground this will result in direct or indirect harm to high risk and other patients. Normal use of portable, cord-connected equipment can lead to the risk of leakage current due to wear and tear on cords and plugs. Also, if a connection plug is incorrectly re-attached, exposure to leakage current will result. These anticipated conditions and the resulting leakage current can cause heart failure.

Studies on leakage current in humans show that leakage current will cause heart failure in certain patients, especially for high risk patients. However, everyone involved with patients or present in these areas are exposed. For example, if a healthcare worker touches a piece of equipment with higher than safe leakage current and also touches the patient, the patient and the healthcare worker will be put at risk. If a piece of equipment is worn or damaged, the likelihood of shock or energy hazard increases. (1)

"The JCAHO (Joint Commission on Accreditation of Healthcare Organizations), has also never taken a firm position on certification and testing of medical equipment, instead, relying on each organization to police

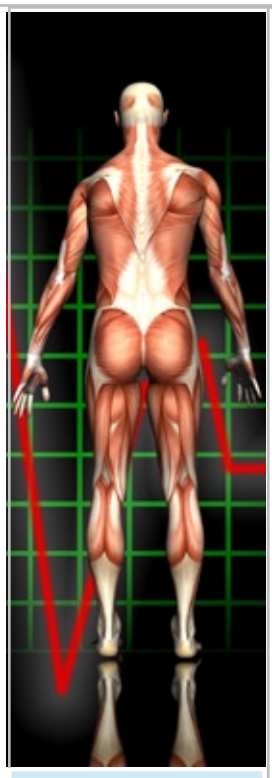
Electrical Safety Standards are written due to deaths, and / or because of obvious, imminent, scientifically verifiable threats to human life and well being. This applies to many aspects of product safety, including grounding, dielectric voltage withstand, leakage current, short circuit, abnormal conditions, single fault / multiple fault temperature / overload, explosion, radiation / chemical hazards, incorrect use of components and more.

For medical equipment, the primary standard for many years was UL 544, Safety of Medical and Dental Equipment. (2) This standard also requires that power supplies be certified as protecting any low voltage circuits, and often requirements for medical grade cords, plugs and other components. UL 544 was a UL (Underwriters Laboratories) standard, a consensus product safety standard, and was created with cooperation from product safety engineers, design & manufacturing specialists, medical / biomedical and inspection authorities. Products that met this necessarily strict standard became the best performers in healthcare, and the US and international safety agencies. In the last edition of UL 544, leakage current for ground to chassis was 300 Microamperes, (300uA). Depending on the specific medical device, leakage current limits are as low as 10uA. For example, a non-patient connected device like a spirometer (connect to the patient by a plastic tube / air only) requires a maximum of 300uA leakage current from chassis to ground. An electrosurgical generator, for example, is in direct patient contact with applied voltage, so the limits are extremely low, in some cases as low as 10uA. (3) UL 60601 is the US version of an internationally "Harmonized" Standard, from the original (International) IEC601. The US version contains national "deviations" to account for differing voltages and national requirements for the United States. The leakage current limits and electrical safety requirements are very similar to the UL 544 limits. The advantage of the Harmonized Standards is the ability of testing laboratories to complete the final items for US certifications. Despite the differences, the requirements for leakage current are now the same worldwide. Another result of this harmonization is that X-Ray equipment, including portable X-Ray units, are now subject to the 60601 requirements. NFPA99 has similar testing requirements and leakage current limits. (4)

Why is certain equipment not suitable for Medical Use? Why does medical equipment undergo different / more rigorous evaluation and testing than other categories of equipment? Why would unsuitable equipment be moved into OR's ICU's and other patient exam areas?

For medical equipment, added safeguards and testing is required. There are many areas where such equipment (referred to as "medical grade") needs to be used: Operating Rooms, Emergency, Intensive Care Unit, and all patient care and exam rooms. Listed medical equipment often has special markings, such as "Do not use in the presence of flammable anesthetics", and "Grounding reliability can only be achieved with the use of a Hospital Grade receptacle". When you see this kind of equipment and Hospital Grade receptacles in the facility, then you will know that other equipment in these areas must meet the requirements for medical use, such as computers, computer monitors, x-ray film viewers, etc. (5)

Many pieces of equipment do not belong in these areas, such as: microscopes or other laboratory equipment, regular "consumer" computers, office furnishings or lights not Listed for medical use, and many other products (6) Still, there are many healthcare facilities that have no incoming inspection for equipment, or no one on staff that would recognize a "non-certified" piece of equipment. Many distributors do not even know the difference, while some do know and try to pass off "CE" marking as a certification mark. ("CE" is not a certification mark).



Sometimes, physicians request very new or prototype equipment directly from a distributor or manufacturer, bypassing any incoming inspection by biomedical engineering or purchasing that might be in place. Much of this new equipment has never been tested for safety, and can put the physician and the healthcare provider in the unfortunate position of potentially harming the patients they are trying to help.

There are many examples of Medical equipment suitable for use in patient areas. Cybernet makes a medical grade computer (www.cybernetman.com). Maxant Technologies manufactures medical display workstations (www.Maxant.com). Both of these companies have their products Listed to UL 60601. These manufacturers understand the requirements, and have testing lab certifications specifically for healthcare facilities.

In some situations, it is possible to use equipment not specifically built or certified for patient areas by using a medical grade isolation transformer. For example, Powervar makes a UL 60601 Listed isolation transformer (www.powervar.com). However, if an isolation transformer is used, it needs to be configured so that the equipment plugged into it cannot be easily unplugged and plugged into a wall receptacle. This can be accomplished by using a locking mechanism, a non-standard cord configuration, or by blocking access to the transformer with the use of a mechanically secured cover that requires a tool or key to open.

Federal Law (OSHA) 29CFR1910 requires that all electrical equipment in the workplace be listed or labeled by a Nationally Recognized Testing Laboratory. Other states, jurisdictions and hospitals have additional requirements. Although these laws might not be well known by the general public, those in electrical safety are familiar with them, and understand the importance and life-saving qualities of these requirements. Some will claim that it is OSHA's responsibility to police safety in the workplace. Electrical safety groups such as ACES (American Council on Electrical Safety), have been working with OSHA to promote training of OSHA inspectors to enforce current laws, but it is an uphill battle for several reasons. Due to budget and personnel limitations, OSHA most often visits a workplace after someone has already died. The fact that OSHA does such a poor job of enforcement leaves the workplace owner with all the liability for injuries and deaths.

FDA-problems and misconceptions. The FDA (US Food and Drug Administration) is the government agency concerned with many issues and areas, most having no bearing on safety of equipment. Although there are FDA requirements for medical equipment, these requirements are not generally related to electrical safety of this equipment, rather they focus on correct and reliable operation of equipment.

The FDA has an "incident reporting" database called MAUDE. While this database is interesting, it has no search parameters for electrical injury and death resulting from causes related to product safety. Additionally, this database is a voluntary reporting database for incidents, relying on a variety of different sources. Many of these sources are people who have no training in electrical safety, and are not even minimally qualified to judge the root cause of the incident, much less to determine if an incident was the result of leakage current. In the end, this database is not a reliable source for any scientific analysis of electrical injury or death from equipment.

The FDA also ignores the issue of electrical safety certification to US Standards. Many do not understand that because a device functions correctly does not mean it is electrically safe. Additionally, The Project on Government Oversight reports that decisions by senior FDA officials in 2006 eliminated critical measures that keep manufacturers of medical devices compliant with high quality standards. (7). Many other problems with the FDA make it a highly questionable source for research on the subject.

Our Biomedical / Clinical Engineering departments are a major force protecting our patients and healthcare staff. These specially trained and hard working technicians and engineering professionals are working every day to insure the safety and proper operation of equipment for our procedures and operations. Their diligence and commitment to patient safety is generally unseen and under-appreciated, much like product safety certification experts.

Biomedical engineers and technicians perform preventive maintenance of portable equipment. These duties include repair and maintenance (cords, leads, equipment subject to abuse…), leakage current, grounding, and other tests depending on the equipment being used. They also ensure equipment is operating properly so that patients will not be put at risk from faulty equipment. Grounding is the weak link and doorway to leakage current injury. Regular tests are critical to ensuring these conditions do not put our healthcare workers and patients at risk. Frequency of tests required or recommended by product varies from 3 months to two years, depending on the type and use of the equipment. This is a well-known fact in the biomedical engineering field.

Additionally, many hospital Biomedical and purchasing departments inspect all incoming equipment for third party certifications and also to be sure the equipment is listed to the correct Standard. In many hospitals across the country, these departments regularly identify non-certified equipment. This non-safety certified equipment represents extreme hazards to everyone, especially when they have passed no initial tests during product certification, and have no limits for leakage current or any other safety tests. These Biomedical and purchasing departments are on the front lines of electrical safety in healthcare facilities. Recently, these departments have been reporting the use of regular consumer computer equipment in patient areas as being non-certified, but their objections have been ignored by hospital administrators.

Many deaths due to electrical shock and current have occurred since the widespread use of electricity. In the 1960's, the issue of leakage current came to the forefront, resulting in the increased level of safety we now have in place. Many articles were written on the subject. (8). There are many ways electrical shock can occur in a healthcare facility, for example, humidity in the plugs of blood and fluid heaters causing device failure (9),Accidental toppling of a fluid container causing spillage onto a blood pressure monitor (10), Electric shocks to anaesthetists after touching a faulty device and the chassis of another device simultaneously (11), An anaesthetised patient was connected to an ECG device that had been wired wrongly with the earth and neutral connections transposed. (12)

How widespread are cases of death by exposure to Leakage Current? This information is difficult to obtain due to several factors: Patients simply die of "Heart Failure" with no further detail provided. Many of these patients are high-risk, and are exposed to electrical equipment in regions of the country where hospitals do not have biomedical engineering departments, and equipment. Many deaths go unreported, or are incorrectly reported, but may actually be caused by Leakage Current.

Correct equipment vs. cost. Computers are everywhere, and the number needed in a healthcare facility can make a computer equipment budget difficult. In recent years, the "cost first" approach has been driven by many departments and their budget managers. Computers and monitors made specifically for medical are more expensive. Why more expensive? What makes something a correct piece of equipment for a healthcare facility, especially patient areas?

The risk level and complexity of medical equipment requires expert design. This mean the designers need to be better educated and higher paid employees. If a company does not have these employees on staff, this cost is reflected in the needed time from special contract employees or consultants.
Equipment suitable for medical use also requires a manufacturer to buy specific correct specialized components, such as low-voltage protected power supplies, better insulated wiring, special enclosures and control electronics. This means that the manufacturing process will be more expensive, including the cost for regulatory inspections, production line testing and factory audits.

All these factors affect the price of this class of equipment, specially designed to treat injury, help improve quality of life and extend many lives.

US Safety NRTL system and the "CE" and "SDoC" threats. A US Nationally Recognized Testing Laboratory is a third party agency that ensures the highest level of safety and security needed for electrical products. Conversely, SDoC and CE are not Product Safety programs. A current issue of serious consequence for healthcare facilities (and also consumers) is the repeated attempts by special interest domestic and foreign computer manufacturing groups to gain acceptance of SDOC. This special interest group is again pressuring OSHA to allow these products to be sold on the market as equivalent of a US (UL or equivalent) Listed product. SDoC stands for "Suppliers Declaration of Conformity". This is a "Self Declaration" program, similar to the "CE" sticker self declaration. This means that a company from anywhere in the world can simply declare their product meets the international electrical safety standards. In the testing laboratory business, we see these "self declared" products come in for evaluation and certification for North America on a regular basis. Some of these products are so far away from being compliant they represent an immediate hazard, especially for fire and electric shock. Recently, the EU has considered an additional product safety mark because of faulty, counterfeit and misrepresented products coming in from Asia. For the US, this SDoC program would mean that these cheaply-made, non-tested products like computers will end up in our homes and in our healthcare facilities. (13)

This fact remains: Equipment that is not suitable for medical use can put patients and healthcare providers at risk for electric shock and death. In the Product Safety Consensus Standards writing process, there are two considerations for writing specific sections and values for exposure to electrical current and voltage. The first is a list with names of people who have died because of this hazard. The second is the scientific proof that without a particular requirement there would be an additional list of people who have died. Both of these issues are currently difficult to quantify and substantiate. To suggest that critical testing, such as leakage current, should be stopped is like arguing that since cars have airbags we can save money by removing seat belts.

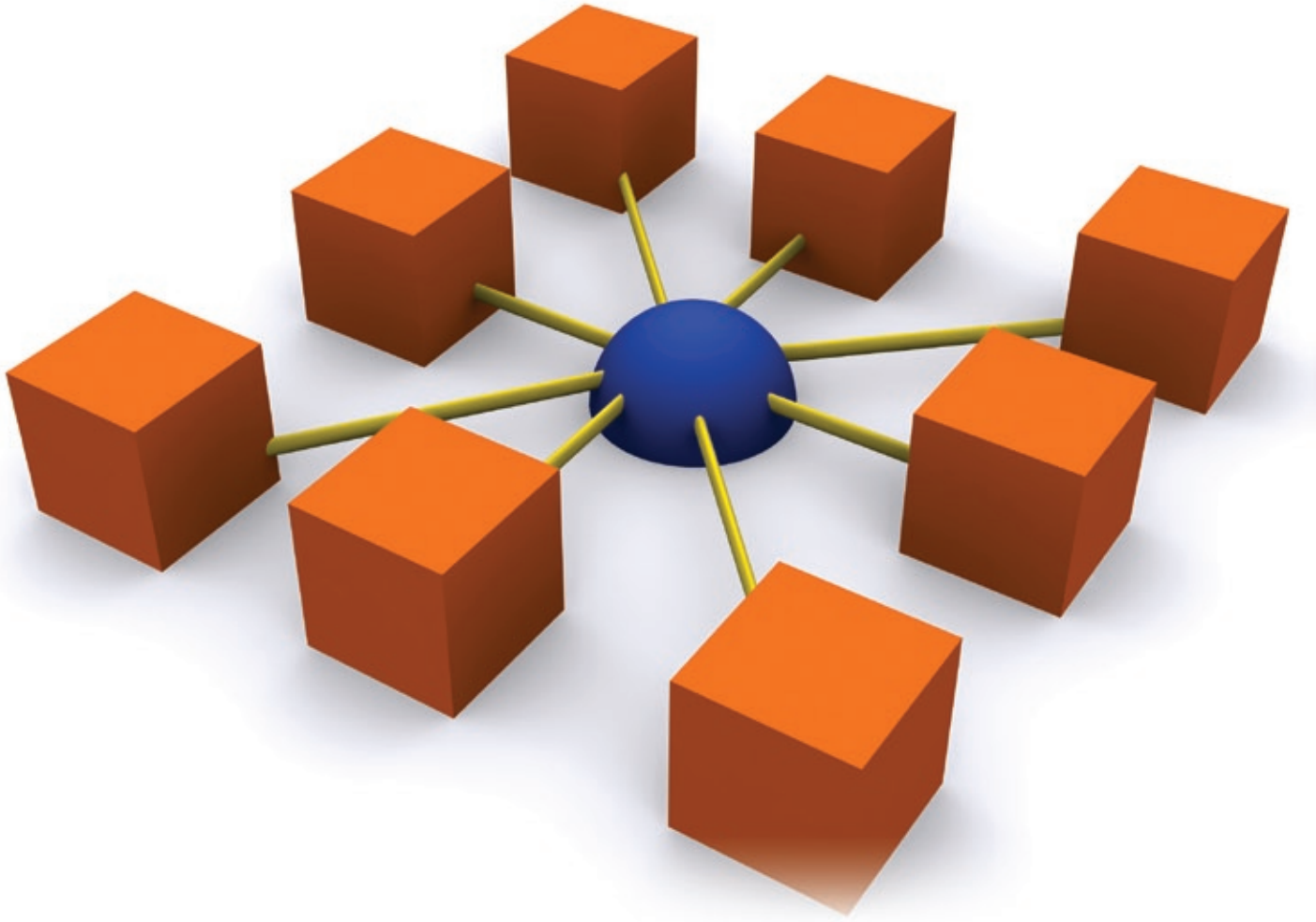
The writers of NFPA 99 understood the value of periodic testing of leakage current, especially for portable equipment, which is subject to particular abuses and wear. The leakage current requirements in NFPA 99 are similar to our UL 60601 product standard. This is why the ASHE position on Leakage Current testing is especially troubling and dangerous. In their proposal to cut sections of NFPA 99, they state that these requirements are being cut in order to "…manage risks while bringing efficiencies to the regulatory compliance burden faced by healthcare providers." In other words, this is being done to cut costs. Any "re-engineering" of NFPA 99 should absolutely consider the existing US Product Safety Standards, (e.g.UL60601) and their scientific basis.

When an electrical product or system loses it's ground, patients and staff are immediately exposed to leakage current. As research has shown, AC leakage current can cause complete heart failure at low levels. Portable Listed medical products employ heavy duty cords and plugs to help avoid the loss of ground, however this condition is inevitable, especially when a piece of equipment is kept in service for many years. No one questions the physicist coming in to check the viability and correct operation of equipment that uses radiation. Conversely, since our track record with electrical incident and deaths has improved because of the correct application of US Standards such as UL60601 and NFPA 99, electricity has indeed become "invisible" and because of this success the practices of electrical safety are questioned.

With counterfeit products from Asia and special interests pushing things like the SDoC program, now is the time for increased vigilance, not for softening or the elimination of time-tested safety standards and product testing. The ASHE attempt to influence JCHAO and dilute NFPA99 should be closely scrutinized and their vested interest and motivations identified and monitored.

The laws of physics cannot be changed to suit a particular purpose. Lives saved by accomplishments of product safety and hospital biomedical professionals are in the thousands, possibly millions by now. The science behind prevention of death from electricity has guided the requirements of national and International safety standards. The history of electrical safety for medical equipment is the history of US industry, engineering, government and testing laboratory professionals developing consensus safety standards. These requirements cannot be sacrificed to suit the plans of any special interest group.

Bibliography available upon request.



Its time for you to Network with us

North Carolina Biomedical Association

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Patrick Lynch, CCE, CBET

Will the manufactures never learn?

In a company, at the corporate level, it's about profit and loss, market share, and margins

After 20+ years of trying to form alliances and nurture trusting win-win relationships with manufacturers and vendors, I'm starting to get cynical.

We all know that we wouldn't have jobs if there weren't technology companies to develop, design, build, and sell medical equipment. But don't they make enough money on the initial sale to keep the company going? Why do so many of them do everything in their power to keep sucking money out of the hospital forever?

I'm speaking of a relative minority of companies. For the sake of avoiding a lawsuit, I won't mention any of the worst offenders here. We all know who they are. Curiously, the most uncooperative companies seem to be the most financially successful.

Everything boils down to money. $$$ It's the common denominator about which almost all things in life can be measured and compared. In a company, at the corporate level, it's about profit and loss, market share, and margins. At the regional level, it's about meeting sales projections. Begin thinking like a company and you're half way home.

If you control (or at least strongly influence) the money that your organization gives to a company, you control the company and how they act. If you have no effect on their money, you don't exist. It's as simple as that.

And there are three distinct areas where you can affect a company's money. 1) when the hospital is purchasing new equipment, 2) when the hospital is deciding support options for the equipment, and 3) when the hospital is looking at the purchase of consumables for the equipment. Are you involved in all three of these areas? Are you a major player in all of these areas? You should be a major player in all three areas.

We, as BMETs, haven't taken advantage of our growing influence. Let me share with you several ways which I have found successful to either manage uncooperative companies, or to avoid dealing with them altogether.

First – Send your money to a friend – not an enemy. Don't give your business to companies who have a history of poor performance or support. If they won't cooperate with you or your hospital, that might offset the advantages of otherwise superior equipment. In order to influence purchases, you must have an active, ongoing relationship with your departments. If you are seen as the technical guru – the problem solver – then you'll usually know when a purchase is being contemplated.

Second – Build a legal framework to support your needs. Build in some really strict terms and conditions for new equipment purchases. The goal here is to withhold a significant portion of their money (more is better) until you receive everything you need. Remember – the purchase order is a legal document which the hospital is obligated to follow, so it must be crafted to support your needs.

Third – Become the key which unlocks the checkbook. Make sure your hospital doesn't release payment for any capital medical equipment until you authorize it. This way you can make sure the order is complete, works well, and all purchasing terms are adhered to. (Open up and read all "Service Manuals". I've found that lately, manufacturers are intentionally mislabeling operator manuals as service manuals. Remember – all service manuals are not created equal.)

Fourth – Publicize poor performing equipment and uncooperative companies. Share information so that other BMETs can learn from your experiences. It used to be that manufacturers could be experiencing repeat problems, but are telling everyone in the field that "You're the only place where this is a problem." With the advent of the Internet and especially the BiomedTalk Listserv, every vendor or manufacturer problem should be posted. This is by far our best weapon against misinformation. Also, if we can get the major manufacturers to watch the ListServ (as most already are, but some won't admit it), they will be careful of what they try to do. If they try something and there is an immediate, nationwide uproar from the Biomed community, they will rethink and possibly change their plans. (If you are afraid of retaliation by publicizing something, send the info to a friend and let them post it in for you.)

Fifth – Never think that you know it all. Remember that when money is at stake, there will be new twists and turns to the games they play. We can never rest on our laurels, but must be ever vigilant for the next scheme business plan which manufacturers will devise to separate hospitals from their money. New products and new uses for old products are being introduced daily. Read every trade journal, sales literature and Internet posting carefully. Even if you think an item doesn't interest you now, your special knowledge will be of use to you sooner than you think. Become an information sponge.

Sixth – Know how far to trust people. Remember – salesmen are ALWAYS more loyal to their company than to your hospital.

Independently, BioMeds have the opportunity to influence the purchasing decisions of their hospitals. Collectively, we have the opportunity to mold the type of healthcare technology WE want to see, by rewarding friendly players and punishing unfriendly ones. All of you out there make me a whole lot stronger than I could ever be by myself, so take the time to share information with the rest of us. Find out how to subscribe to the BiomedTalk Listserv and be an active contributor.

Concord NC welcomes 2009 NCBA Symposium

Come Join Us at the Embassy Suites in Concord

Our 31st Annual NCBA Symposium is fast approaching and the NCBA Board of Directors is hard at work arranging a great lineup of classes and presenters for you this year. You may have noticed in the previous issue of Calibrate, and on our website that the location of the symposium has changed.

For many years we have held our Symposium at Pinehurst but during the last several years we have been experiencing some growing pains. Our Corporate members and vendors have been very patient with us while we tried to work with Pinehurst to increase and improve the space for the show. We have tried patiently to work with them to work these issues out but after several years we have not been able to find a solution that we felt met our needs.

This has been a topic of discussion at every Board of Directors meetings for the last several years and after the problems we had last year we felt it was time to make a change. After visiting multiple locations and reviewing the pros and cons of various facilities around our fine state the Board felt that the Embassy Suites in Concord was the best choice for the location of our next Symposium.

This fine facility has the most to offer our membership in terms of meeting space and amenities as well as many wonderful assets in the area for your enjoyment. Our golf tournament will be held at the Rocky River Golf Course this year and many of you may want to visit the Lowes Motor Speedway right next door. Please check out their websites at http://www.embassysuitesconcord.com/index.html and http://www.lowesmotorspeedway.com/ .

You should find this location lots easier to get to for those of you flying in from around the country since it is only a short distance up I-85 from Charlotte. Please look for more information on our class offerings and about registration on our new website in the next several weeks. We look forward to seeing you at this year's event.

Information for Advertisers

Our newsletter is now completely digital. Since we will no longer be printing and mailing our newsletter some things have changed in our ad policy. For the remainder of this year your membership in the NCBA allows you two half-page ads in the newsletter. All issues will now be in full color so we would appreciate it if you could send us an up to date color version of your ad as soon as possible. Our policy on the size of ads remains unchanged. we're pretty flexible about the ads physical size. The newsletter is printed in a "portrait" orientation and because of the layout and the margins, the biggest ad we can accommodate is 7.5" wide and a typical half-page is about 5" high at that width.
For members that wish to run additional ads and for non- members costs for ads are:

Full page
$200.00 per ad
Half page
$100.00 per ad
Quarter page or less
$50.00 per ad

If your ad is a different size or orientation we can arrange the text around it. Just keep the overall size to around 38-40 square inches. If we have to change the size, we will try to keep it in the original proportions and as close to the original size as the page will allow.
The best format for an ad is either JPEG, TIFF or Photoshop PSD. We strongly suggest an image resolution of 300 dpi – anything less will produce an unacceptable grainy image. We use Adobe Photoshop CS3, Adobe InDesignCS3 and Adobe Illustrator CS3 to produce the newsletter and InDesign will import most MS Word text documents, but the results are mixed when graphics are included. Sometimes it looks just like the original and other times InDesign gets confused and the imported document does not look anything like the original. A JPEG, TIFF or PSD graphic file (single layer) will always work well. If you use fonts that we do not have, the end result will be uncertain if the fonts are embedded in the graphic - flatten all layers before saving. Printed "camera ready" copy can be scanned for insertion in the newsletter, but better results are obtained by working from the graphic file. If you have to send "camera ready" copies by mail, please send two copies in a rigid mailing envelope to minimize physical damage.
We will post the high resolution version of the newsletter to the website around the 15th of each odd-numbered month and will need your ad by the last day of the previous even-numbered month. Once you have sent an ad we will save it for future use till you specify otherwise - you only need to let us know what issue you want it to run in. If you do not have a preference, we will run the ad when the content of the newsletter gives adequate space. Call me at 919-475-5794 (M–F, 8am–5pm) or e-mail if you have any other questions. If you are unable to e-mail the files,