MU Health disputes investigators’ findings of dirty instruments

By JODIE JACKSON JR.

When state health inspectors concluded an examination of University Hospital’s surgery department late last year, hospital officials issued a statement that said inspectors discovered a variety of housekeeping deficiencies: broken and discolored floor tiles, dust, dirty floors in food service areas and peeling paint or plaster.

After all, local officials said, the hospital was built in 1956, and it has a few cracks and discolored tiles in patient and non-patient spaces “where we needed to get in and do some sprucing up,” spokeswoman Jo Ann Wait said.

Roughly half of the 65 observations those inspectors made on behalf of the Centers for Medicare and Medicaid Services (CMS) focused on housekeeping items. But when the hospital made the report public in January, it was clear inspectors saw more than just dirty floors, broken tiles and food crumbs. In fact, several findings regarding dirty surgical instruments mirrored those in a report from a Food and Drug Administration inspector who flagged contamination issues in the hospital’s sterile-processing department in 2008.

The CMS report found that the hospital’s surgery department was not in compliance with the agency’s infection control standards, meaning continued noncompliance could result in not getting paid for treating Medicare patients — nearly 40 percent of the hospital’s patient base.

MU Health officials disagreed with the FDA observations and with many of the CMS findings, but administrators implemented corrective action, including a massive deep-cleaning of the hospital one weekend involving some 120 employees as a result of the CMS report. The hospital also added 25 housekeepers to increase maintenance and cleaning operations.

MU Health Care CEO Jim Ross also pointed out that CMS determined the complaint that led to the surprise inspection was “unsubstantiated with unrelated deficiencies.” Hospital officials have responded to the CMS and FDA reports by saying there is no evidence patients were harmed by conditions the reports alleged.

“They themselves did not indicate any patient was at imminent risk,” said Carey Smith, MU Health manager of regulatory affairs. “We have focused our quality improvement efforts on outcomes that matter to patients.” MU Health officials said last week in a written response to a reporter’s questions. “Our patient care outcomes data, including low surgical site infection rates and low bloodstream infection rates, provides strong evidence of the effectiveness of our patient safety and infection control practices.”
Les Hall, MU Health’s chief medical officer, pointed out that the hospital’s rate of staph infections has declined dramatically each year since 2002.

Neither the CMS nor FDA reports had bearing on the Joint Commission on Accreditation of Healthcare Organizations’ decision to grant full accreditation — and a gold seal of approval — to MU Health Care on Nov. 10, five days after the CMS report was issued.

The FDA report was based on eight inspection dates from May through July 2008. A key finding — reprocessing of devices meant for single use in surgery and other similar procedures — was the one hospital officials most disagreed with. The FDA regulates devices that are typically designed for only one use. The instruments can sometimes be reprocessed — or resterilized — but only with FDA approval and only by meeting stringent requirements for record-keeping, training and other factors.

“It has never been the policy of University of Missouri Health Care to reprocess single-use instruments,” Wait said on Friday. “We disagreed with the 2008 FDA surveyor observations.”

Wait said the surveyor, Monique Brooks, mistook reusable instruments for single-use devices, or SUDs. Wait also said another inspector from the FDA completed a one-day visit to University Hospital on Feb. 10, concluding there was no evidence to indicate reprocessing of SUDs.

“They said we were clean,” Wait said.

FDA communications officers have not confirmed that conclusion, and Wait did not provide a written report. But in 2008, there was clear evidence — presented in sworn affidavits of hospital staff members, photographs and other documents provided to the FDA — that the hospital’s sterile-processing department was routinely reprocessing single-use devices.

If any employee was disciplined or terminated because of the reports by regulators, the hospital isn’t saying. “Out of respect for the privacy of our employees, it’s our policy not to discuss personnel matters,” Wait said.

THE FDA REPORT

Nearly half of the 400-some-page FDA report was redacted because, in the words of FDA communication officers, it contained the identity of employees, employee information, manufacturer identity and other details considered not necessary for public disclosure.

Internal e-mails among MU Health officials, obtained through a Freedom of Information Act request to the FDA, clearly show that sterile-processing and surgery department managers weren’t sure whether SUDs were being reprocessed. Amy Tinsley, director of surgery services, sought input from other hospitals on how they differentiated single-use from reusable instruments.

“If your hospital/clinics utilize disposable instruments, such as suture removal kits, how do you clearly differentiate the one time use instruments from your normal instrumentation in sterile processing?” Tinsley wrote on May 23, 2008, two days after the FDA inspection began.

Another of Tinsley’s e-mails, copied to Mark Jackson, director of surgery, said, “Physicians and staff place these instruments back in reprocessable instrument trays and send them to sterile processing. They are VERY difficult to differentiate from re-usable instruments, causing the SPD unit to unknowingly process a one-use item.”
The FDA report also supported Backues' claim and documentation showing that repair reports and maintenance checklists dating back to early 2007 showed lack of action from the maintenance department.

Brooks concluded in her report that she found "significant in-house reprocessing of single-use devices." Backues filed an online complaint with the FDA against the hospital on May 1, 2008. The final report said the devices were found "as indicated in the Med-Watch report." A number of the instruments intended for one use were being reused for eye surgeries, such as cataract procedures.

The FDA report also found: instruments that were "rusty and with residue," "numerous rusty drill bits and one rusty retractor on orthopedic trays," "rusty instruments (single-use and reusable) in various surgical trays after the wash and decontamination," "supposedly sterilized instruments in peel packs that were visibly corroded or rusty" and filters used to clean instruments were "dirty with debris and other unknown substances." The report said there was no documentation showing when the filters were last cleaned.

**THE CMS REPORT**

More than two years after Monique Brooks completed the inspection hospital officials have since disputed, the CMS investigation turned up more issues, some of which echo those in Brooks' report.

On Nov. 1, 2010, state health inspectors noted that in the same-day surgery department, a layer of thick dust coated the surface of an anesthesia cart and a camera located above the surgical table. "When the surfaces were wiped, dust particles fell to the floor and onto the surgical table," the report noted.

Before inspectors left, they recorded 65 observations, some of which were duplicate notes. Once again, "dirty instruments" were listed. In the same-day surgery department, a "sterile" pack that contained a hook used in eye surgery was dirty, and there were particles in a sterile tray.

The report said the infection control nurse did not know where the particles were from "or if there was a concern if these particles became a foreign body (something that does not belong in a patient's body) during surgery."

Inspectors also noted dirty floors in surgical suites at Women's and Children's Hospital, "thick dust" on equipment in the burn intensive care unit and outdated medical supplies in the neonatal intensive care unit.

The report said the dirty floors were brought to the attention of the infection control nurse, who said, "Floors are not a source of infection; it is an aesthetic issue." The nurse also confirmed dust was "a problem we have seen before."

Inspectors also made several observations of inadequate handwashing hygiene, a measure considered by most infection control managers to be the No. 1 way to prevent hospital- and health care-associated infections.

Other observations in the CMS report included:

- Failure to meet sanitary standards for surgical suites, procedure rooms, kitchens and similar areas created conditions "potentially affecting staff, visitors and patients."

- "Dirt, food crumbs and dust blackened the corners, borders and tile rout" in a kitchen at University Hospital.

- A number of outdated sterile devices and other outdated supplies, some dating back to October 2005.
• "Failed to ensure the integrity and cleanliness of surgical suites, procedure rooms and sterile processing department."
• "Residue and debris on sterile instruments in sterile surgical containers."
• "A dirty and grimy sink in the Sterile Processing Department work area."
• A device containing bloody abdominal drainage was placed in the trash can in a patient’s room, without emptying the contents down a drain.
• "Dirty instruments in sterile trays, specifically orthopedic (bone) trays.” In one documented case, “three out of three trays in one day had instruments with bone or cement on them.”
• Technician washed dirty surgical instruments with gloves on, then opened a door and answered the phone without removing the wet gloves.
• "Urinal containing urine sitting on the overhead table where the patient’s personal items were and where patient eats."

Marcia Patrick, director of infection prevention and control for MultiCare Health System in Tacoma, Wash., and also a board member with the Association for Professionals in Infection Control and Epidemiology Inc., or APIC, said the examples of poor handwashing and the nurse’s statement about floors not being connected to infection control were "inexcusable.”

Patrick said the dirty surgical instruments “may or may not cause an infection, but that’s a chance you shouldn’t take.”

Backues said sterilizing equipment can “bake on” blood and tissue not cleaned off instruments

“If it’s harboring germs,” Patrick said, “and if germs come into contact with the wound, it could set up for an infection.”

Jeanine Thomas of Illinois personally knows about getting an infection from a surgical incision. She coordinates World MRSA Day every October to bring attention to methicillin-resistant staphylococcus aureus — or MRSA, a “superbug” that can cause deadly infections.

Thomas survived a MRSA infection in 2000 that resulted from surgery for a badly broken ankle.

“We believed that hospitals were clean. We just believed we have a high level of health care in the U.S.,” said Thomas, 55, who worked with then-Sen. Barack Obama to help pass her state’s Hospital Report Card Act that requires, among other things, screening of all intensive care unit patients for the MRSA bug.

“We believed we were being protected. It’s a shock to realize that they’re not,” she said. “We have dirty hospitals.”

Hospitals should welcome independent audits of their infection control systems, she said.

“If you’ve done everything you could have or should have done to prevent these infections, why would you oppose that?” Thomas said. “This is about patient safety — doing what’s right for the patient first, not what’s best for the hospital. It is about saving lives.”

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University of Missouri police are investigating a report of a rape that happened outside of Laws Residence Hall early Tuesday morning.

Capt. Brian Weimer said MUPD received the report at 6:39 a.m. Tuesday. A female victim said between 4 and 5 a.m. Tuesday she was approached by a white male who appeared to be an older college-aged student with a short haircut. Weimer said in a news release.

The male started asking her questions, assaulted her and then raped her. After the incident, the male ran south toward university parking lot WG 6, the release said.

Anyone with any information is requested to call Detective Michael Laughlin at (573) 884-2605, or CrimeStoppers at 875-8477
For women living with HIV, a picture isn’t just worth a thousand words; it can be worth an entire voice, a University of Missouri researcher is finding.

Michelle Teti, an assistant professor of health psychology in MU’s School of Health Professions, is using photography to help women with human immunodeficiency virus tell their stories, even when they find them difficult to talk about. She is conducting a study in St. Louis that equips women with cameras to let them document their lives.

Teti conducted a similar project in Philadelphia, allowing women with HIV to snap photographs of themselves and their environments. Some women opted to take pictures of themselves looking healthy and strong to combat stereotypes that those with HIV are frail and sickly. Others took photographs of their streets and homes, including one woman who took photos of her broken kitchen appliances to highlight her substandard living conditions.

Teti began applying photovoice — a methodology used since the 1990s that lets certain populations photograph their lives — to women with HIV after working for several years in public health prevention. Women with HIV, she said, did not have many opportunities to talk about their lives.

“Women with HIV face more challenges than most intervention programs are designed to address,” she said. “These women need to discuss more issues than merely how to have safe sex. Many live in poverty, with substandard housing and abusive partners. Helping women understand and address these issues is what this project is all about.”

Teti plans to conclude her follow-up study in St. Louis this summer. Although the project still is in a pilot phase, she’s hopeful the methodology can be applied to health prevention programs.

Columbians will have a chance to see photographs from Teti’s Philadelphia project during the True/False Film Festival, which starts Thursday. The exhibit will be displayed at the Forrest Theater on the mezzanine of the Tiger Hotel.

Festival co-director David Wilson said the project should add a “neat flavor” to the film festival. “There’s a great tradition of documentary photography, even more so of self-documentation, something that’s been an exciting idea in film and photography in recent years.”

Teti then plans to display the collection of photographs at an AIDS awareness event in St. Louis later this month.

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Hallsville man pleads guilty in MU attack

A Hallsville man was sentenced to five years in prison yesterday for a July assault of a woman near the University of Missouri campus.

Jeremy Greber:
Sentenced to five years
Jeremy L. Greber, 25, pleaded guilty to felonious restraint.

He and his public defender tried to convince Circuit Judge Gary Oxenhandler to suspend his sentence because of Greber's clean record, but the judge would not have it.

"It's not going to happen," he told counsel. "What he did was horrible."

Instead, Greber was recommended by Oxenhandler to a 120-day treatment program.

The defendant could serve the remainder of his sentence on probation upon completion of the program and Oxenhandler's approval.

Greber was arrested on suspicion of felonious restraint and third-degree assault with physical injury.

He turned himself in at the Columbia Police Department the day after the assault, telling police he could not recall his actions from when he left a downtown bar the night before until 7 a.m. that morning, according to court documents.

Greber told police he turned himself in because he saw his picture — taken from surveillance video — in news reports.

University police responded to the area of University and Hitt around 2:20 a.m. July 31. Greber placed the victim in a "bear hug," according to court documents, and both suffered abrasions as he attempted to gain control over her while on the ground.

Video surveillance from the Hitt Street parking garage captured images of Greber walking next to the victim before the incident and Greber alone after the incident, the documents said.
NorthStar Medical Radioisotopes: Signs agreement with Missouri University to supply Molybdenum-99

(MADISON, WI. – March 1, 2011) – NorthStar Medical Radioisotopes, LLC (NorthStar) announced it has signed an agreement with the University of Missouri Research Reactor (MURR) to supply NorthStar with low specific activity molybdenum-99. This agreement allows NorthStar to ramp up over time to 3,000 6-day curies per week. Production operations are expected to begin 3QTR of this year with shipments to pharmacies shortly thereafter.

NorthStar’s approach helps to resolve the molybdenum-99 supply challenges by producing low specific activity (LSA) molybdenum-99 without using uranium as the source material. NorthStar’s process utilizes a stable non-radioactive isotope of molybdenum (molybdenum-98) that produces significantly less waste by-products that are easily handled and disposed of.

LSA molybdenum-99 produced will be transferred to NorthStar’s patented TechneGen™ Generator System, a key technology in making this process viable. The high specific activity (HSA) technetium-99m produced will meet the United States Pharmacopeia requirements. NorthStar’s goal is to begin domestic production of molybdenum-99 alleviating dependency on foreign sources. “The TechneGen process provides a unique tool in a compact format that make routine processing at a nuclear pharmacy safe, effective, and reproducible” stated NorthStar’s Chief Science Officer Dr. James T. Harvey.

“We at NorthStar believe that our technology will establish a more secure, cost effective and redundant domestic source of molybdenum-99,” said George P. Messina, NorthStar’s President. “Combining our TechneGen technology with the reliable services of MURR provides an unparalleled approach to establishing a domestic source of this vital medical radioisotope within the next few months.”

“MURR is pleased to support NorthStar. Providing irradiation services aligns with our mission, expertise and experience.” said Ralph A. Butler, MURR’s Director.

About NorthStar Medical Radioisotopes

NorthStar Medical Radioisotopes was founded in 2004 to pursue development of technologies and provide tools that would be instrumental in bringing rare radioisotopes to the nuclear medicine market. The TechneGen Generator System is one such tool. NorthStar’s programs include enabling the research community to continue their clinical trial efforts in the development of therapies to fight diseases such as cancer and HIV. In addition to molybdenum-99, NorthStar is currently developing technologies to produce, among others, actinium-225 (whose daughter bismuth-213 is considered a promising cancer therapeutic and is also a possible therapy for HIV), actinium-227 (for the treatment of metastatic bone cancer from Hormone Refractory Prostate Cancer), and tungsten-188 (for the treatment of melanoma). (http://www.northstarmm.com)
COLUMBIA MISSOURIAN

Nobel Prize winner delivers keynote at MU science symposium

By Camille Phillips
March 1, 2011 | 8:34 p.m. CST

COLUMBIA — Roger Tsien is not a brain surgeon, but he did win a Nobel Prize for developing a process that has the potential to make brain surgeons better at their jobs.

Tsien, a professor at the University of California, San Diego, gave the keynote speech at the Translational Neuroscience Symposium at MU on Tuesday afternoon. He gave his speech before a full house in the Bond Life Sciences Center's Monsanto Auditorium, with about 30 more people listening in a spillover room.

The speech highlighted the most recent developments in the research that won Tsien the Nobel Prize in chemistry in 2008 — the uses of fluorescent proteins to see cellular processes that would otherwise be invisible.

Tsien said the research is "not yet feasible in humans" because human cells are too thick and the process would require gene-transferring. If that hurdle could be jumped, fluorescent proteins could be used to guide surgeries to cut out tumors, allow for earlier detection of cancer and show where plaque is in arteries.

By staining the tumor green and neurons blue and overlaying those images with a video during surgery, scientists were able to more easily remove the tumor and avoid the neurons. Tsien showed a video of his assistant using that technique to remove a tumor from a mouse to demonstrate how easy it was and how much it increased her confidence.

The studies done with mice showed that using this technique reduced the reappearance of tumors and increased the success of the surgery, Tsien said.

Tsien enlivened his speech with several interesting comparisons. He called proteases — proteins that can break down other proteins — in cancer cells "molecular machetes" because they allow cancer cells to cut through healthy tissue. It is this ability, he said, that allows cancer to spread to other parts of the body, which can lead to death.
At another point, Tsien compared adding fluorescence to a name tag sticker. He said that adding a negative charge to the fluorescence allowed him to control where the fluorescence attached itself, much like the backing on a name tag stops it from sticking until it is removed. In the mice, the tumor had a substance that cut the negative charges and lit them up.
MU receives second-place rank for dorms

By JANES SILVEY

The University of Missouri has the second best slate of residential halls in the country, according to a new review from CampusSplash.com – a website that explores everything from college admissions to the latest fashion trends on campus.

The site has created the Dormy Awards, ranking the best and worst residential halls in the country. MU landed just below first-place Georgia State University on the list of the 14 Schools with the Best Overall Dorms.

Also on that list, Washington University ranked No. 10 and Truman State landed at 14. KU ranked sixth.

You can check out all of this year’s Dormy Award winners, and losers, here.