Two hospitals in the Duke University Health System put patients in “immediate jeopardy” last year by failing to detect that surgical instruments were being washed in used hydraulic fluid instead of detergent, according to the Centers for Medicare and Medicaid Services (CMS).

A copy of the CMS report, completed in March, was obtained by OR Manager. The report details inspections at Duke Health Raleigh Hospital, Duke University Medical Center, and Durham Regional Hospital.

**Corrective action plans**

The hospitals submitted corrective action plans, which were accepted by CMS, and are now considered in compliance with Medicare rules.

The mix-up happened after a company servicing elevators at the hospitals discarded hydraulic fluid in empty detergent drums. The drums were later picked up by the distributor, taken back to its warehouse, and shipped out to 4 hospitals. At 2 of the hospitals, the drums were hooked up to washer-disinfectors used to clean surgical instruments, where hydraulic fluid was used in place of detergent for several weeks. The oily instruments that resulted were used on about 4,000 patients.

Duke wrote the patients to inform them of the incident. Duke’s CEO, Victor Dzau, MD, said in a June 15 statement there has been no notable increase in infection rates, and “an outside expert has corroborated that the sterilization process was not compromised.” He said Duke asked scientists to conduct a chemical analysis of instruments processed with the oily fluid. In late June, Duke sent patients another letter saying the analysis showed there was a very small amount of residual fluid on the instruments. Of metals tested for, most were not detectable, and a few were “barely” detectable, according to press reports. Duke also announced it would provide a list of the chemical ingredients in the hydraulic fluid to any affected patient who requested the information.

A North Carolina newspaper, the News Observer, reported June 12 that a number of patients “are reporting lingering health problems,” are dissatisfied with Duke’s response, and are talking to lawyers.

**CMS traces error**

The CMS report traces how the error occurred. CMS officials visited the facilities and interviewed staff and administrators.

In the summer of 2004, elevators were refurbished. The used hydraulic fluid was placed in empty drums labeled Mon-Klenz, a detergent made by Steris Corporation. The elevator company left the drums at the hospital for future pickup. In September, an administrator noticed the 10 to 12 shrink-wrapped drums sitting on a pallet in the parking lot. He called environmental services and engineering, which in turn called other departments.

On Oct 2, the drums were picked up by the distributor, Cardinal Health, and taken to its warehouse, but no paperwork was exchanged, CMS found.

In December, Cardinal shipped some of the drums to 4 Duke hospitals where “all drums were accepted without questions at each facility,” CMS reports. Though the drums were not sealed, that fact was not identified.

Thinking the drums contained detergent, staff at Duke Health Raleigh and Durham Regional connected them to washer-disinfectors.

Soon after, Central Service (CS) and OR staff began to notice “oily basins and oily instruments.” They told CMS inspectors they reported their concerns to management multiple times.
‘Frustrated and ticked off’

One staff member at Duke Health Raleigh reported feeling “frustrated and ticked off that no one would listen.” CS staff said the residue created “double work” because they had to rewash loads by hand and were falling behind.

One CS staff member told the CMS inspector the instruments were “way too greasy.” This staff member said the Central Service manager asked, “What are you doing wrong?” The staff member told him the instruments kept coming out greasy, and the staff was doing the best they could to clean them again. The staff member said the manager told them to “wipe them down better,” but the instruments “never stopped being greasy,” according to CMS.

Eventually, after about 8 weeks, the error was found in a check by the biomedical engineering department and a Steris rep. A similar problem was discovered at Durham Regional.

Where the process broke down

Among deficiencies CMS identified, which the facilities addressed in their corrective action plans:

• failure to oversee services of the elevator company and the distributor
• lack of a policy on reuse of containers or on defacing labels on containers that are reused
• lack of a receiving process in Central Service to ensure seals on products are intact. (Ordinarily, Mon-Klenz drums have a seal that needs to be removed with a special tool.)
• no written documentation on staff complaints or evaluation of the complaints
• when instruments came out oily, not following the manufacturer’s trouble-shooting instructions, which say to “check detergent; incorrect detergent”
• not conducting observations and audits of the cleaning process after staff reported oily instruments
• not training CS staff on using the hospital’s voluntary reporting system for problems
• failing to address continued complaints of “oily instruments” after initial trouble-shooting was ineffective
• not contacting a service rep in a timely manner
• not initiating additional monitoring of the “oily” instruments to determine if they were safe after the problem was identified
• failure of staff to communicate concerns and reports to upper management in a timely manner
• failure by department managers to report inability to correct the problem to the hospital administration.