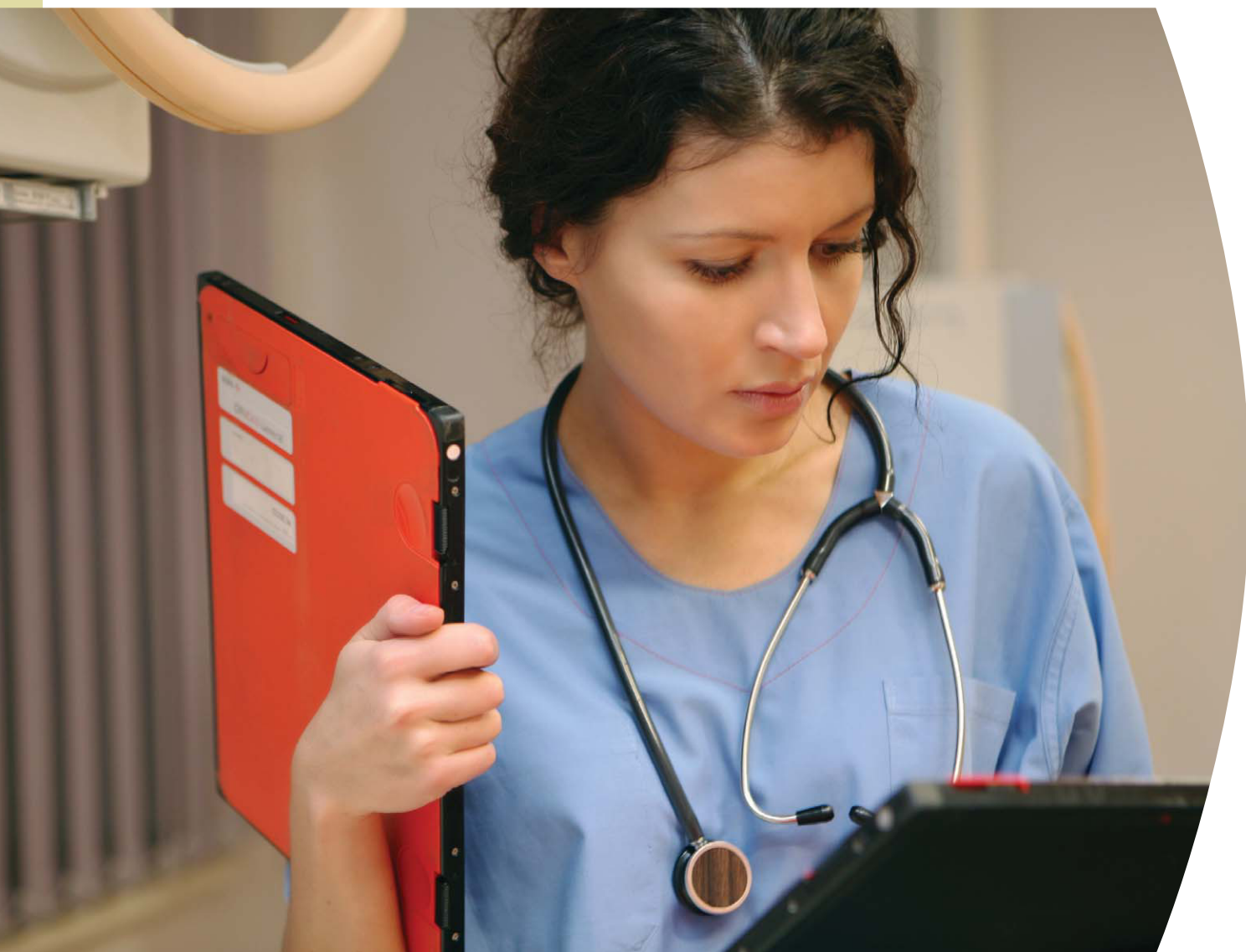


The New Hospital Accreditation: *Case in Point*

Claire Lee, RN, MSN, CNAA, CPHQ



Ball Memorial Hospital (BMH), a Clarion Health Partner in central Indiana, is the only facility between Indianapolis and Fort Wayne. The hospital has 2,500 employees with a payroll exceeding \$95 million. As the senior ad-

ministrative director of quality and safety at BMH, I had the opportunity to speak to a local group comprising industry quality control and process engineers. My topic was about statistical control in healthcare.

After the meeting, I took them on a tour of the cardiac catheterization lab. They were fascinated by the processes we had in place to ensure a quality product for our customers. We had always focused on the clinical aspects of our service, but they were studying our production processes—equipment selection, product control, measurement, and calibration. We had departments that focused on that, but it really wasn't emphasized in our quality management program. Basically, we took a lot of that for granted. One of the engineers, an ISO-9001 auditor, told me, "You have wonderful processes in place here. You should apply for ISO certification." That was 5 years ago. I really had no idea what he was talking about; I thanked him for the feedback and stored it in the back of mind.

It wasn't until 2007 that I spotted a news article on ISO 9001 certification for healthcare and thought back to that comment. Thus began our journey. I contacted DNV Healthcare Inc. (then known as TUV Healthcare Specialists) and learned that their goal was to create an alternative hospital accreditation program incorporating the ISO 9001 quality management system with the Medicare conditions of participation (CoPs). I was fascinated and invited DNV to come to BMH to introduce the concepts of ISO 9001 to our leadership group, and that set the wheels in motion. Everyone was enthusiastic. We have had a strong performance improvement program at Ball Memorial, but ISO took us to the next level. The inclusion of every department of our organization, clinical and nonclinical, created a cohesive vision with true constancy of purpose.

We set a target to obtain ISO 9001 certification by October 2007, and we achieved our goal. Once DNV was awarded hospital accreditation deemed status by the Centers for Medicare and Medicaid Services (CMS), we took the next step, and in October 2008, we were awarded DNV's hospital accreditation (NIAHO, National Integrated Accreditation™ for Healthcare Organizations). We are currently dually accredited by both The Joint Commission (TJC) and DNV.

What are the differences and similarities between the two organizations? Both offer 3-year accreditations, use tracer methodology, and bring in physician, nurse, administrative, and life safety surveyors. Both are about quality and safety, and both are surveying against the Medicare CoPs. Where they differ is in the *base* from which they survey, the survey frequency, and the scoring process. TJC surveys against their standards every 3 years; DNV surveys annually against the ISO 9001 clauses every year. As Thomas K. Gardiner, MD, executive vice president for clinical development at BMH, put it, "The emphasis is on the application of engineering processes designed to reduce variability and improve standardization. Ultimately, it is the reduction of error and, in our world, reducing harm to our patients."

BMH adopted a philosophy of continual readiness many years ago. We conducted patient tracers and quality/safety rounds monthly. These activities primarily covered the clinical departments. To meet the ISO 9001 standards, we had a number of things to put into place. Our primary need was to develop an audit process for all departments. That meant we

ISO requires an annual audit of every department and every process by internal auditors, organizational staff who audit departments that are not their own.

needed to involve areas such as accounting, purchasing, and registration, areas that previously had never been reviewed. Even the quality/safety department is under review, not for what is produced, but for the processes within the department used to produce our "product."

ISO requires an annual audit of every department and every process by internal auditors, organizational staff who audit departments that are not their own. We asked for employees to volunteer to serve as internal auditors. We had an immediate outpouring of interest from all departments and levels. Currently, 27 internal auditors conduct the annual audit for close to 75 departments. We had tried a number of times in the past to break down information silos but never really succeeded or, at any rate, never sustained it. Using the ISO internal audit process has encouraged people from all over the organization to visit departments they would never have entered and to find out not only how they do things but why. As a result, all departments now have a better understanding of who does what and why.

Our first internal audit revealed a number of concerns that had never been addressed, but when the auditor raised concerns, it was as if a light went on and problems were immediately corrected. The reviews also fostered an environment of collaboration and reduced interdepartmental friction.

ISO 9001 also required us to develop an effective document control system (DCS) that included all policies/procedures, forms, records, and other supporting documents. This was a major undertaking that probably will never end. The DCS is integral to ISO and the DNV survey process, for without controlled documents, how do we ensure that we're operating from the most current version? How often have you found an outdated preprinted order sheet on a chart or a staff member using an outdated procedure/work instruction?

When asked by the DNV administrative auditor what did ISO do for us, Patient Accounts Manager Debbie Mace couldn't have put it more succinctly: "It brought my department into the fold, and it forced me to document processes that had never been documented. My staff is oriented to the written

We have taken our quality management system to the next level, adopted a language that is universally understood by our stakeholders, strengthened the bonds between clinical and nonclinical departments, and in doing so, have reduced variability and error.

procedure, monitored against the written procedure, and everything is done the same way. If someone fails to show up for work, anyone can step in and follow the correct process.”

Although both TJC and DNV expect us to conduct root cause analyses and failure mode and effect analyses (FMEA), ISO 9001 speaks in terms of corrective and preventive action plans. These plans are broader in scope and require documentation every time a nonconformity (deviation in the process) occurs. Many more preventive action plans have been initiated at department levels than ever before. We are in the process of relocating five departments into a new building, and the relocation team (on their own) scheduled an FMEA to identify suicide risk in that environment. As a result, a number of processes were developed that would not have been identified under our previous approach.

Unless there are major violations of the Medicare CoPs or an absence of the primary components of ISO 9001 (which require immediate response), all DNV findings require a corrective action plan that must be submitted within a designated time frame and will be audited during the next annual audit. There is no opportunity for improvement thresholds or degrees of accreditation.

ISO 9001 is very much understood by our local community. Our board members understand it, can speak to it, and value it. Many of them are from ISO-certified industries. Our patients work in ISO-certified organizations, and they understand it. It's not uncommon for feedback to come with terms like “very standardized process” or it was (or was not) “an ISO experience.”

The DNV survey experience was both collaborative and educational. Six auditors arrived unannounced to conduct a

4-day survey. Other than a review of our required ISO documents and the usual survey documents (e.g., open and closed medical records, policies, and procedures), the entire DNV survey team was out and about conducting patient tracers and interviewing departmental staff about their work and reviewing compliance with the Medicare CoPs. Everyone was at ease. Staff from nonclinical departments were interviewed about what they did, how they did it, and how they were taught. They were asked if they had documents to support what they did and what would happen, for example, if they won the lottery and didn't return—would someone be able to step in so that the process would be unaffected?

All in all, DNV fosters an atmosphere of partnering. As Sherrill White, RN, CPHQ, one of our PI coordinators and an internal auditor, observed: “In a very basic way, DNV-surveyed nursing staff feel that the weight of the survey is not totally on their shoulders. We all know that many variables affect the delivery of care. Some influences may slow staff's ability to provide patient care or make tasks more cumbersome with inefficiencies or products that do not perform as expected. While TJC touches on many of the contributing factors, DNV looks at every department that has any direct or indirect connection to our ‘product:’ patient outcomes.”

We believe the inclusion of ISO 9001 has been the real value-added feature. We have taken our quality management system to the next level, adopted a language that is universally understood by our stakeholders, strengthened the bonds between clinical and nonclinical departments, and in doing so, have reduced variability and error. From my global perspective, the greatest benefit to our organization is DNV's focus on ensuring all units and departments (clinical and nonclinical) have a common ground so that all personnel understand, and “the right hand *really* does know what the left hand is doing,” summed up Marianne Kritzer, senior administrative director for cardiology services. **NL**

Claire Lee, RN, MSN, CNAA, CPHQ, is the senior administrative director for quality/safety at Ball Memorial Hospital in Muncie, IN. She can be reached at cleec@chsmail.org.

1541-4612/2009/ \$ See front matter
Copyright 2009 by Mosby Inc.
All rights reserved.
doi:10.1016/j.mnl/2009.03.010