Quality Qorner

Can You Hear It?

When the Harry Potter books first came out I totally ignored them, feeling that I should be concerned with more worldly things, like laboratory quality. My idea of magic and fantasy was the "Chronicles of Narnia," which I first read in grade school. Indeed, I shared a first name with one of the key characters; my childhood best friend, Susan, and I were the queens of Narnia, if only in our minds and youthful play games.

A few years ago I was a guest in someone's home when I saw the first Harry Potter movie. Instantly captivated by the imaginative fun of it all and recognizing the opportunity for some laboratory-free, brain-vacation airplane reading, I immediately immersed myself in the magic of the books, awaiting each new one as eagerly as any young person. The related films have provided hours of delightful entertainment.

In one film, there's a point where Ron is sitting at the long table for breakfast with his housemates when a bird flies in through the window and drops an envelope in front of his face that hovers there in midair, a lovely parchment envelope, closed with red sealing wax. Suddenly, the wax and flaps transform into red lips that start screaming at Ron in his mother's voice. Ron has just received a "howler" and everyone knows it. She's admonishing him for something that should not have happened.

This scene came to mind as I was trying to describe to an audience of rather younger technologists the importance of capturing and analyzing laboratory occurrences, known as "nonconforming events," in quality language. These events should not have happened; that is, they represent deviations from the expected results of your laboratory's established policies, processes, or procedures, whether or not they could have harmed—or did harm—a patient. Our laboratories' usual immediate response to such events is to remedy the situation as quickly as possible, put it behind us, and move on to fighting the next fire, solving the next problem, or remedying the next nonconforming event.

So, think of your laboratory's nonconforming events as "howlers." Each one is screaming at you about a problem—an erroneous result, a lost sample, a complaint, test results generated from what was later found to be outdated reagents, and all the other problems so commonly encountered in the laboratory. Just as in the movie where the howlers are hard to ignore, your laboratory should not ignore your own. They carry important messages about which of your laboratory's processes are not functioning properly.

Nonconformances most often represent failures of badly performing processes, not bad people. Therefore, one of the downfalls of the remedy approach is that the same howlers reappear in our faces, meaning that we haven't really solved the underlying problem at all. The reason is that laboratories often lack a systematic approach to handling nonconformances. However, you now have an opportunity to learn about and implement such an approach that may rid you of unwanted and unpleasant howlers.

The Clinical and Laboratory Standards Institute (www.clsi.org) recently published a guideline titled, *Management of Nonconforming Laboratory Events,*[1] which was prepared by a committee of volunteer professionals from medical laboratories, government, and industry. The guideline provides a suggested outline and contents for a program to help your laboratory glean a deeper meaning from the messages of your never-ending howlers. The program describes:

- Identifying and reporting: Discovering an event and initiating a report.
- Taking remedial action: Resolving the immediate concern
- Investigating: Obtaining and recording more detailed information.
- Classifying: Using classification schemes to aid in analysis and follow-up.
- Analyzing and presenting data: Aggregating data and presenting graphically.
- Reviewing and referring to process improvement: Determining and removing the root causes.

Also included are several forms that can be used or customized for your laboratory's staff to report and investigate nonconformances. The forms are adaptable to computer screen formatting and the entire approach is adaptable to a tracking system that your laboratory could develop from an office suite database application or could instead purchase from a commercial software vendor.

Having a systematic approach to identifying and following up on your laboratory's "howlers" is a laboratory accreditation requirement. This new guideline will help with implementation, to the benefit of your customers and patients.

You know, it takes a lot of energy to come up with a new idea for this column every month. So, if you'll excuse me now, I'm going to take a break, indulge my childhood memories of magic and mayhem and catch the second Narnia movie.

1. Clinical and Laboratory Standards Institute. *Management of Nonconforming Laboratory Events; Approved guideline GP32-A*. Wayne, PA: CLSI; 2007.

This Month's Quality Quote:

"Trouble is opportunity in work clothes."

—Henry J. Kaiser

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