

The effect of ISO 15189 implementation for the reduction of incidents

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The way to strengthen medical safety have been attracting attention to deliver definite and accurate clinical laboratory data to physicians^{1,2)}. ISO 15189 is an international standard that specifies the quality management system (QMS) requirements particular to medical laboratories, and ISO 15189 has been reported to play an important role in quality improvement and prevention of examination errors³⁻⁸⁾.

Recently, we reported about our experience for the effect of ISO 15189 implementation for the reduction of the number of incidents⁴⁾. We experienced that the total number of incidents decreased significantly even one year after accreditation. In the literature search, similar observations were reported⁵⁻⁸⁾, and in this Editorial, we are going to introduce these papers describing the effect on the reduction of the number of incidents after accreditation of ISO 15189.

First paper is from Yoshiko et al⁵⁾, from Nagoya University Hospital. They acquired ISO 15189 accreditation in November, 2009. They revealed that post-accreditation, the number of nonconformities and incident reports were decreased. They revealed that the number of incidents were decreased from 100 in 2009, to 94 in 2010. They also revealed that the level 0 and level 1 incidents increased in 2010 (level 0, 13% in 2009 to 18.3% in 2010; level 1, 48% in 2009 to 53.8% in 2010), whereas level 2 and level 3a incidents decreased in 2010 (level 2, 32% in 2009 to 24.7% in 2010; level 3a, 2% in 2009 to 1.1% in 2010), also suggesting that ISO 15189 works well for reduction of number and level of incidents. Additionally, they pointed out some problems related to the post accreditation of ISO 15189, which is the increment of

the complaints from the staffs and increase of overtime works to operate QMS⁵⁾.

Next paper is from Shitara et al⁶⁾, from Kosei general hospital. They acquired ISO 15189 certification on December 1, 2005. Although they did not investigate the level of the incidents precisely, they revealed the total number of incidents decreased obviously (year, cases; 2003, 57; 2004, 65; 2005, 26; 2006, 25; 2007, 24)⁶⁾. They also found that, more than 80% of the incidents occurred through 2003 to 2007 were from “5.4 pre-examination processes”, “5.5 examination processes”, and “5.8 reporting of results” in the standard requirements of ISO 15189, and the proportions have not been changed throughout this period⁶⁾. In addition, the proportions of incidents in each process were relatively similar to those in a previous report⁹⁾.

Third paper is from Ota et al.⁷⁾, from St. Mary’s hospital. They acquired ISO 15189 authorization in December 2007. They revealed that total incidents in 2007 was 240 cases whereas 62 cases in 2010, which is three years after accreditation⁷⁾. What was characteristic in their report was, in the process of authorization acquisition, they tried to improve ward nursing management using ISO 15189, drew up standard operating procedures through detailed job analysis, and enabled ward operation standardization⁷⁾.

Last paper is from Okada et al.⁸⁾, from Okayama University hospital. They got ISO 15189 accreditation on July, 2007. In the year of 2005, two years before their accreditation, the total number of incidents was 116. Then the number was decreased to 84, in 2006 and 2007, and finally dropped to 48, a year after accreditation. They concluded

ed that the frequency of laboratory incidents was reduced through seeking the causes of incidents and performing continual improvement according to ISO 15189: “Plan, Do, Check, Act”. They also described that the motivation and competence of laboratory staff concerned have also improved, consequently leading to a favorable influence on other laboratory staff members.

Collectively, all of these published five papers clearly demonstrate that implementation of a QMS meeting ISO 15189 standards is effective for the reduction of incidents. As far as we searched, no paper has been found for the negative effect of ISO 15189 on medical safety. The effect of this implementation may take several years for the sufficient effect for the reduction of incidents. Recently, ISO 15189:2012 has been updated to ISO 15189:2022, with increased emphasis on risk management¹⁰⁾. All of reports presented in this paper are based on ISO 15189:2012, or earlier, version of ISO 15189. Therefore, we are now expecting that implementation of this new ISO 15189:2022 QMS will further improve measures for medical safety.

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