Shorts on Standards: ISO 22367: Application of risk management to medical laboratories

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May 2020—Hazard. Harm. Risk. Benefit. Performing any activity poses risks. The laboratory deals with hazards known and understood, or unknown and unanticipated, that can lead to harm. Laboratorians attempt to minimize these risks to the point where benefit exceeds residual risk that cannot be further minimized. We understand these concepts and terms and deal with them in everything we do. For optimal patient care and for the safety of our employees, a formal approach to risk assessment is desirable to identify pertinent risks, assess those risks, determine if and when the risk has been sufficiently minimized or if mitigation measures are worth the benefit we expect to see, and document each step.

In vitro diagnostic device manufacturers use ISO Standard 14971:2019 for risk management in the development and marketing of their products. This document directs the evaluation and control of recognizable risks in the products they produce, and identification and quantification of residual risks that remain after minimizing the risks they've identified. The development of ISO Standard 22367:2020 "Medical laboratories—application of risk management to medical laboratories" is based on the manufacturer's standard; however, it was recognized that although IVDs are common and important in the clinical laboratory, there are many activities that are not based on commercial IVDs, and the risks associated with these activities must also be managed. Consequently, ISO 22367 addresses risks of IVD use in the laboratory, as well as risks associated with the processes and procedures that medical laboratory operations encompass.

ISO 22367 presents the following structured approach to risk management in the context of a quality management system:

- Definition of risk as both the frequency with which a hazard occurs as well as the severity of harm that may result when a hazard occurs.
- Acceptability and/or control of risks, initially and when problems occur.
- Recognition that controlling an identified risk may cause or worsen other associated risks (unintended consequences).
- Evaluation of residual risk.
- Balance of perceived benefit against residual risk that still presents significant hazard.

As a tool for understanding one's processes and addressing problems beyond immediate corrective action, risk management is an effective approach to assessing hazards and associated potential harm in a complex environment. ISO 22367 guides the application of risk management specific to the clinical laboratory with the intent of identifying, evaluating, and controlling such risks.

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committee.