Checklist of Best Practice for Risk Management

Full Name: **Email:** **Organization:**

Does your existing QC process meet the following recommendations?

		✓	×	?	M.O.R.E. Quality™ (Mathematically-OptimiZed Risk Evaluation)
	1. ISO/IEC Guide 51 Safety aspects -- Guidelines for their inclusion in standards				
	1. Risk is the combination of:				**The medical director controls, and software manages:**
1a	[A] the probability of occurrence of harm and				A. probability of harm by setting acceptable risk criteria as the number and cost of Medically-Unreliable Results (MURs) per year, and per failure event.
1b	[B] the severity of that harm				B. severity of harm by setting limits of medical utility (medical goals) – and the associated cost of failure to meet those goals - for each analyte by clinical setting.
	2. USA CLIA 42 CFR 493.1445 – Standard; Laboratory Director responsibilities				**M.O.R.E. Quality™ Risk Management**
	2. The Laboratory director must ensure that:	✓	×	?	
2a	The test methodologies selected have the capability of providing the quality of results required for patient care."				Set TEa limits only as locally-approved medical goals for each clinical setting and acceptable risk criteria at evidence-based attainable levels.
2b	Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and Laboratory personnel are performing the test methods as required for accurate and reliable results;				Recommends using the same medical goals and acceptable risk criteria for method evaluation and ongoing quality control.
2c	Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;				Compares acceptable # MURs and clinical/legal cost to medical goals and acceptable risk criteria at each method review, every 1-4 weeks.
2d	Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;				Clearly says "STOP" if methods fail acceptable risk criteria. Verifies effectiveness of the QC process in use by simulating failure of acceptable risk for daily QC as part of each routine review.
2e	Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly.				Software auto-advises corrective action in analytical or QC processes and links staff to specific faults to investigate to improve accuracy and/or precision. Daily QC is routinely verified to be able to detect failure.
	3. ISO 15189:2012 Medical laboratories - Requirements for quality and competence				**M.O.R.E. Quality™ Risk Management**
	3. Allowable Total Error	✓	×	?	
3	**The allowable total error** is equivalent to the error that does not significantly contribute to wrong clinical decisions.				Sets allowable total error limits – and the associated cost of failure to meet those limits - only at values that must be approved by the medical director in conjunction with local "PIPS", patients, institutions, physicians, and society - for each analyte by clinical setting.

ISO and CLIA	✓	"YES"
	×	"NO"
CLSI EP 23-A	?	"I DON'T KNOW"

Learn more about M.O.R.E. Quality™ at www.awesome-numbers.com

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	Does your existing QC process meet the following recommendations?				M.O.R.E. Quality™ Risk Management
	4 & 5. CLSI EP 23-A. Laboratory Quality Control based on Risk Management				
	4a to 4e Definitions & Requirements for Risk Management	✓	×	?	
4a	"**Incorrect result –** result that does not meet the requirements for its intended medical use; NOTE 1: In the case of quantitative test procedures, a result with a failure of measurement that exceeds a limit based on medical utility."				Simulates failure of acceptable risk criteria to meet medical goals and verifies the ability of QC to detect unacceptable risk with each routine review, every 1-4 weeks.
4b	"**Acceptable risk –** a state achieved in a measuring system where all known potential events have a degree of likelihood for or a level of severity of an adverse outcome small enough such that, when balanced against all known benefits— perceived or real— patients, physicians, institutions, and society are willing to risk the consequences."				Set TEa limits only as locally-approved medical goals for each clinical setting.
4c	"**Control Samples** - Quality control sample – A stable sample designed to simulate a patient sample."				Step 1 in the M.O.R.E. Quality™ is to "Verify QC Samples mirror Patients." It makes no sense to base decisions about acceptability of patient quality on QC results if those samples are not verified change accuracy and precision when patients do.
4c	"**Risk evaluation** – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk."				The acceptable number and cost of errors must be approved by the medical director in conjunction with local "PIPS", patients, institutions, physicians, and society. Risk evaluation reports are also available to "The PIPS."
4d	"**Evaluate the potential costs** both in terms of the patient's well-being and in terms of financial liability of the treating parties vs. known benefits to the patient."				Software report risk as the number and cost of patients at risk based on data from a QC sample that is verified to represent patients. Compares to acceptable risk criteria.
4e	"**At the least,** the ability of the QC procedures to detect medically allowable error should be evaluated."				Reports the number and clinical/legal cost of errors with Pass/Fail grades for acceptable risk.
	5a to 5e. The QC strategy using QC samples should include the following for each measuring system	✓	×	?	**M.O.R.E. Quality™ Risk Management**
5a	1. "The frequency of QC sample test events"				Recommends from 1 to 15 QC checks daily for each QC sample based on QC effectiveness and patient test volume, or STOP if the method fails acceptable risk criteria.
5b	2. "The type and number of QC samples tested per test event"				Unlimited QC samples are independently assessed. Number and type of samples is linked to clinical need.
5c	3. "The statistical QC Limits used to evaluate the results"				A single QC rule or statistical limit is recommended based on Margin for Error to unacceptable risk, and verified to flag failure of acceptable risk criteria for daily QC. Can be auto-implemented with interfaced daily QC software.
5d	4. "The frequency of periodic review for detecting shifts and trends"				Recommended QC review frequency increases to improve error detection as Margin for Error decreases
5e	5. "The actions taken when results exceed acceptable limits"				Software auto recommends [1] improving accuracy and/or precision to improve the analytical process - and shows faults to investigat, or [2] STOPPING if the method fails acceptable risk criteria.

	ISO and CLIA	✓	"YES"
		×	"NO"
	CLSI EP 23-A	?	"I DON'T KNOW"

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