Meeting the ISO 15189:2003 Analytical Quality and Performance Specification Requirements

ISO 15189 Number	ISO 15189 Standard Description	What Sites Need To Do To Meet ISO 15189 Standards with the GEM® Premier™ 3000 and iQM™ (GEM-iQM System)	What Instrumentation Laboratory (IL) Provides with the GEM-iQM System
5.7.1	Systematically review results	Evaluate patient and QC data. Patient results are automatically linked to QC data and are always available for review either at the instrument or remotely.	• GEM-iQM automatically performs, assesses, and documents QC data. • Any corrective actions are documented and available for review on the analyzer or remotely via GEM*web*™. • When automated corrective actions are unsuccessful, affected analyte(s) are automatically disabled.

Instrumentation Laboratory

GEMISO.PS 06/04

A Worldwide Standard for Medical Laboratories: ISO 15189:2003 Particular Requirements for Quality Competence

With today's world community—globalization of industry and manufacturing and a very mobile society—mutual recognition of medical results through worldwide testing standards is essential. ISO 15189, the international standard for medical laboratories, addresses this need.

PARTICULARITIES OF ISO 15189 [1,2]

ISO 15189 takes a quality systems approach to address: patient result interpretation; information provided to requesting clinicians; specific quality requirements for pre-, analytical, and post-analytical phases of testing; technical and medical personnel competence; and a variety of issues concerning quality, safety and ethical issues. Specific topics include:

- Appropriate choice of tests for a patient in a given situation
- Sampling instructions and patient preparation
- Preliminary storage and transport to the test site
- Turnaround time and emergency testing
- Examinations by referral laboratories
- Attention for biological reference intervals
- Information on reports and professional judgment
- Technical and medical competence
- Confidentiality aspects

ISO 15189 AND POINT-OF-CARE TESTING (POCT)

Since POCT must conform to the general requirements for all medical laboratory tests, there is no separate POCT standard. However, annex D focuses on distinct needs, such as training of operators, supervision of the process, and potential differences in results generated from POCT devices and those in the routine laboratory. This annex specifies that organizations involved in POCT must evaluate and monitor the devices just as methodologies and instruments in the central laboratory are evaluated and monitored. For optimum effectiveness, the central laboratory must play a major role in POCT to ensure that instrument maintenance, calibrations, and ongoing quality control/QA checks are being performed. Standardized protocols must be available and followed by all operators and an audit trail established that links patient test results with the analyst, instrument and quality checks. ISO 15189 mandates training and states that good communication between clinicians and everyone involved in the POCT process is essential to prevent problems, particularly with the introduction of new POC test methods. In those cases where the committee considers POCT to be useful, the comparability of results between different POCT devices and central laboratory methods must be established. Central laboratories can and should play an important role in the management of quality for POCT

ADVANTAGES OF ISO 15189

Finally there is a worldwide, accepted standard (ISO 15189) on quality requirements for laboratory medicine. Through a universal, worldwide standard, the medical laboratory profession can improve its quality image and credibility. The requirements in the standard are general, but they can be applied in all medical laboratory sub-disciplines including POCT.

REFERENCE

1. Libeer, JC, Ehrmeyer, SS: ISO 15189: A Worldwide Standard for Medical Laboratories. *Point of Care* 3:1; 5-7, 2004.

2. ISO 15189:2003. Particular Requirements for Quality and Competence in Medical Laboratories. Geneva, Switzerland: International Organization for Standardization; 2003

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4.2.4	Have a quality manual that describes the quality management system and includes: a quality policy, staff education/training, quality assurance, document control, instrument reagent management, validation of procedures/results, protocols for sample collection and handling, quality control, result reporting and remedial actions.	As part of this documentation, assemble the quality, quality assessment and improvement policies/procedures necessary to collect patient specimens, initially validate and monitor the GEM Premier 3000's entire analytical system and report patient test results.	• GEM Premier 3000 Operator's Manual • All reagents and controls are IL supplied and contained in the disposable analytical PAK. • Each analytical PAK is verified independently by a series of NIST-traceable external solutions called CVP. • GEM-iQM automatically initiates corrective actions, disables the affected analyte(s), re-enables the recovered analyte(s), and notifies the operator about the analyte(s)' status.
4.2.5	Establish and implement program, which regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. Have a documented and recorded program of preventative maintenance and calibration which, at minimum, follows manufacturer's recommendations.	Nothing	• All instrument actions are documented. • GEM-iQM requires no maintenance. • All analytical processes from sample aspiration to result reporting, including monitoring sensor stability (calibration), performing QC analyses and evaluations, and conducting a variety of instrument function checks are totally automated. • There is no reagent preparation and GEM-iQM continually monitors all onboard solutions. • GEM-iQM automatically initiates corrective actions including disabling the affected analyte(s), re-enabling the recovered analyte(s), and notifying the operator about the analyte(s)' status. • Known analytical interferences have been evaluated and documented in the GEM Premier 3000 Operator's Manual. • Some interfering substances in patient samples are detected by iQM Failure Pattern Recognition software. • The operator is alerted when tolerances are exceeded or problems occur.
5.5.3	Have documented procedures describing how to perform all procedural steps available to relevant staff.	Assemble a procedure manual that describes the entire testing process including reporting of patient results and test site-specific information.	• GEM Premier 3000 Operator's Manual. • GEM Premier 3000 Standard Operating Procedure (SOP) diskette.

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5.6.1	Design internal QC systems that verify attainment of intended quality of results.	Test site director or designee approves the use of the GEM Premier 3000's pre-established QC* limits, which are bases on total allowable error requirements and instrument performance specifications. *IL's bulk QC solutions are called "Process Control Solutions (PC Solutions)"	• GEM-iQM automatically analyzes a minimum of 2 levels of QC every 4 hours and a third level every 24 hours. • PC Solution B continually monitors sensor stability. • GEM-iQM continually evaluates QC data and notifies the operator when results exceed tolerance limits. • GEM-iQM automatically performs corrective actions when tolerance limits are exceeded and disables the affected analyte(s) when self-correction is not achieved. • All information is documented and available on demand.
5.6.3	Design a program for calibration and verification of trueness to ensure results are traceable to reference constant.	Test site director or designee decides on the acceptability of the GEM Premier 3000's calibration, accuracy and precision that are verified with each new analytical PAK. Participate in interlaboratory external assesment programs that independently document accuracy.	• Calibration and verification of sensors' accuracy in a cartridge are being performed using three PC Solutions that are traceable to NIST standards. • Process stability check is also performed to verify stability of PC Solutions during the cartridge life. • With installation on instrument, the calibration of each cartridge is verified independently by a completely different series of external solutions called CVP. • PC solutions monitor stability of the verified calibration throughout the "life" of the cartride. • For further validation of accuracy across the range of calibration, Performance Verification Product (PVP) may be purchased from IL (5 levels for blood gases, electrolytes and metabolites; and 4 levels for Hct).
5.6.4/5.6.5	Participate in interlaboratory comparisons (quality assessment schemes) or develop a mechanism to determine acceptability of results when EQA are not available.	Subscribe to external quality assessment programs for the analytes tested.	• GEM-iQM analyzes the EQA samples in the same manner as patient samples.