COLLEGE of AMERICAN PATHOLOGISTS

Risk Management Guide

ISO 15189 Accreditation Program

Background

The ISO 15189:2012 standard includes a clause regarding risk management (4.14.6). The text reads:

"The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken."

To clarify the laboratory's responsibility and the CAP's assessment standards, the CAP has developed this guideline.

CAP Guidance Summary

ISO 15189 assessors from the CAP will ask to see risk assessments of any new or significantly revised processes implemented in the laboratory. Assessors may also ask to see evidence of an ongoing program of risk management; this includes activities such as internal audits, occurrence management, proficiency testing (PT), and quality control (QC). Assessors will evaluate the effectiveness of the laboratory's risk management activities in light of all findings from the assessment, including corrected results, internal audit results, occurrence management data, and customer complaints.

Key Definitions

TERM	DEFINITION
Failure Mode	The manner in which a process could potentially fail (ISO/TS 22367)
FMEA	Failure Mode and Effects Analysis
Process Owner	Person who has the ultimate responsibility for the performance of a process in realizing its objectives measured by key process indicators, and has the authority and ability to make necessary changes
Risk	Combination of the probability of occurrence of harm and the severity of harm (ISO 14971)
Risk Analysis	Systematic use of availiable information to identify hazards and to estimate the risk (ISO 14971)
Risk Assessment	Overall process comprising a risk analysis and a risk evaluation (ISO 14971)
Risk Evaluation	Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk (ISO 14971)
Risk Management	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating , controlling and monitoring risk (ISO 14971)
Work Process	Set of interrelated or interacting activities which transform inputs into outputs (ISO 15189)

Assumptions

1. Managing risks is not only a process, but a mindset that needs to be present throughout the laboratory. Laboratories need to create a risk management culture.

2. Risk management can be (1) a project triggered by an occurrence or finding, (2) a proactive project to evaluate potential weaknesses in a new, revised, or complex processes or (3) a continuous assessment based on daily events and observation of what is happening in the laboratory.

3. The risk management process typically involves four key stages:

   A. Analyze the laboratory process: Understand it (typically through process mapping) and identify risk points.

   B. Evaluate risk points: Assess them based on probability and severity/impact. Typically this takes the form of a matrix, and assigning a value to the risk. Here is an example of a risk matrix:

Risk Matrix Example

Severity

Probability	NEGLIGIBLE	MINOR	SERIOUS	CRITICAL	CATASTROPHIC
Frequent					
Probable					
Occasional					
Remote					
Improbable					

KEY Unacceptable risk Acceptable risk

Note: Many laboratories find it helpful to provide further definition of the increments of probability and severity/impact. See Appendix A for an example of a scale of probability and severity/impact.

C. Control risks:

1. Determine how to mitigate significant risks by changing the process.
2. Consider whether these risk control measures/process changes introduce new risks, and if so, address them.
3. Choose indicators or monitors that show whether the risk control plan is working (e.g., corrected reports, customer complaints, or TAT).

Note: Once the laboratory has taken these steps, it may need to revisit them. For example, the initial control measures/process changes may not have the desired effect. New measures may be necessary.

D. **Monitor** risks: Follow the data until you see a pattern of resolution based on the indicators chosen in step 3(c) above. Bring the risk down to the point where there are constraints (based on available technology, or budget) that prevent you from reasonably bringing it down any further. There will always be some residual risk.

4. Work processes include more than laboratory tests. They also include processes from the pre-analytical and post-analytical phases, as well as support processes such as document control and procurement. A laboratory's core and support processes are the basis for its internal audits. For an example of a laboratory's processes, see Appendix B.

5. The most important target of risk assessment is core processes that directly impact patient care. Here is an example of such core processes:

PRE-ANALYTICAL	ANALYTICAL	POST-ANALYTICAL
Test ordering	Testing	Result reporting
Specimen collection	Result review	Archiving specimen
Specimen transport	Interpretation	
Specimen receipt		

6. Risk assessment is a requirement for IQCP. You may need to retrieve records and develop a "current state" for test groupings. For established test processes, you may have already completed much of this work (for example, with EQC data).

Routine Laboratory and Quality Team Activities that Reveal Risks

1. **Internal Audits**—These are independent appraisals of work processes by someone who is:
   - Not directly involved in the specific process or discipline
   - Knowledgeable about the general technical domain
   - Trained as an auditor

   Because audits involve direct observation, document and records reviews, and review of results, they can help you to identify many kinds of risks, for example:

AUDIT FINDING/ NONCONFORMANCE	DESCRIPTION	RESULTING RISK	PROBABILITY	SEVERITY
Mislabeled specimens	The specimen accessioning process is not identifying inadequately labeled specimens.	Lab will need to call physician and/or recollect sample, resulting in potentially long delays in test results	3	4
Obsolete documents	The document control process is not restricting access to obsolete documents.	Work activities may not be performed using the current procedure.	3	1-5, depending on process affected
Recurring errors	The corrective action process is not preventing recurrence of errors, or at least minimizing the impact.	Errors will be perpetuated, potentially impacting patient laboratory staff safety and health	3	1-5, depending on process affected
Temperature issues	The refrigeration system is not effective in keeping temperature within a certain range.	Reagents will not perform as intended.	4	4

   Rather than simply applying corrections (immediate actions to contain the nonconformance), such findings should be addressed with risk assessment, root cause analysis, and corrective action.

2. **Everyday Observation**—Being observant and aware of what is happening around you can identify risks. For example:
   - Seeing stained ceiling tiles, and recognizing that this may indicate a leak and/or mold, which could interfere with results
   - Smelling diesel fumes, and recognizing that these are coming from intake vents near the loading dock

   Issues like these need to be assessed in terms of potential impacts on patient care, and their associated probability and severity.

3. **Occurrence Management**—Collecting, totaling, and analyzing occurrences can reveal risks. For example:
   - Analyzing reporting distribution—If you see that a few departments are reporting few or no occurrences, this does not indicate that everything is perfect. More likely, this represents a lack of commitment to reporting, a blind spot in the organization, and a high risk area.
   - Performing root cause analysis—The root cause of an occurrence may have the potential to impact many processes, not just the one in which the error or nonconformance occurred. This identifies risks of additional nonconformances that may occur.

4. **Proficiency Testing**—Analyzing PT results can help identify risks, even if the laboratory testing passes, and its testing status is not in jeopardy.
   For example:
   - High level PT reports review patterns of outliers or failures. For example:
     - o The number of analytes with outliers is increasing over time
     - o There is a specific discipline (eg, hematology) with a high number of outliers, relative to other disciplines
     - o There are specific classes of tests (eg, all the blood gas tests) that show problems
   - Individual survey reports, which detail the performance on a specific test, can be used to identify issues such as trending of deviations, or near misses. (See the CAP 15189 publication "Using PT to Improve the QMS.")

5. **Quality Control**—By monitoring daily results with a Levy-Jennings chart, identifying when the majority of the values are on one side of the mean, or showing a trend, the laboratory is identifying risks within the testing processes, and can intervene early with root cause analysis and corrective action. New IQCP requirements prompt laboratories to identify and evaluate potential problems that relate to individual testing processes.

6. **New, Significantly Revised, or Complex Processes**—It is important to proactively assess the potential weak points in new, revised, or complex processes, and take appropriate action.

How the CAP Will Assess Risk Management

1. If the laboratory is developing new tests, or new processes that will be brought online, assessors will ask to see proactive risk assessments, including:
   a. Process maps
   b. Risk points
   c. Assessments of probability and severity
   d. Actions taken or planned to mitigate risks

   Note: For examples, see Appendix C and D.

2. Assessors may ask to see examples of documented risk assessments relating to core processes that directly affect patient care. These may include those risks identified through:
   a. Internal audits
   b. Everyday observation in the normal course of running the laboratory
   c. Occurrence management processes
   d. PT activities
   e. QC activities, including IQCP assessments
   f. Analysis of new processes, or significantly revised processes, or identification of complex processes

   Note: For an example, see Appendix E.

3. Assessors will evaluate the effectiveness of the risk management process in light of all findings from the assessment, including:
   - Corrected results (these indicate whether the risk management process is working)
   - Occurrence management data
   - Internal audit results
   - Customer complaints and survey data

4. If the risk evaluation for a process is contradicted by other data (eg, the process as a whole or key risk points are identified as low probability/low severity, yet there are numerous customer complaints or internal audit findings), the assessors may request additional information to determine whether the risk management process is effective. (Effectiveness is a requirement of the standard, as shown in 4.14.1 (c)).

Further Guidance/Best Practices

1. Assign a process owner to each of your core processes. Give that person the responsibility for risk assessment of the process, based on the key steps in the standard risk assessment process:
   a. Analyze the process
   b. Evaluate risk points
   c. Control risks
   d. Monitor risks

2. Provide process owners with training in the following areas:
   - Root cause analysis
   - Internal auditing

   These disciplines are essential for performing effective risk management. CAP QMEd courses Root Cause Analysis and Internal Auditing are designed to provide the necessary understanding. https://cap.enspire.com/

3. Document your laboratory's process for risk management.

4. Additional best practices regarding risk management can be found in the following resources:
   - ISO 15189:2012, Medical laboratories—Requirements for quality and competence
   - ISO 14971:2007, Medical devices—Application of risk management to medical devices; specifically Annex H, Guidance on risk management for in vitro diagnostic medical devices
   - ISO/TS 22367:2008, Medical Laboratories—Reduction of error through risk management and continual improvement
   - ISO 31000:2009, Risk management—Principles and guidelines
   - CLSI EP23-A, Laboratory Quality Control Based on Risk Management; Approved Guideline

References

1. ISO 14971:2007, Medical devices—Application of risk management to medical devices; specifically Annex H, Guidance on risk management for in vitro diagnostic medical devices
2. ISO/TS 22367:2008, Medical Laboratories—Reduction of error through risk management and continual improvement
3. ISO 31000:2009, Risk management—Principles and guidelines
4. CLSI EP23-A, Laboratory Quality Control Based on Risk Management; Approved Guideline

Appendix A—Example of a Continuum of Probability and Severity/Impact (from ISO 14971)

Note: The probability table below would need to be adapted based on the laboratry's test volume.

Probability Levels

LEVEL #	COMMON TERMS	DEFINITION
5	Frequent	Once per week
4	Probable	Once per month
3	Occasional	Once per year
2	Remote	Once every few years
1	Improbable	Once in the life of the measuring system

Severity Levels

LEVEL #	COMMON TERMS	DEFINITION
5	Catastrophic	Could result in patient death
4	Critical	Could result in permanent impairment or life-threatening injury
3	Serious	Could result in injury or impairment requiring professional medical intervention
2	Minor	Could result in temporary injury or impairment not requiring professional medical intervention
1	Negligible	Could result in inconvenience or temporary discomfort

Appendix B—Example of a Laboratory's Core and Support Processes

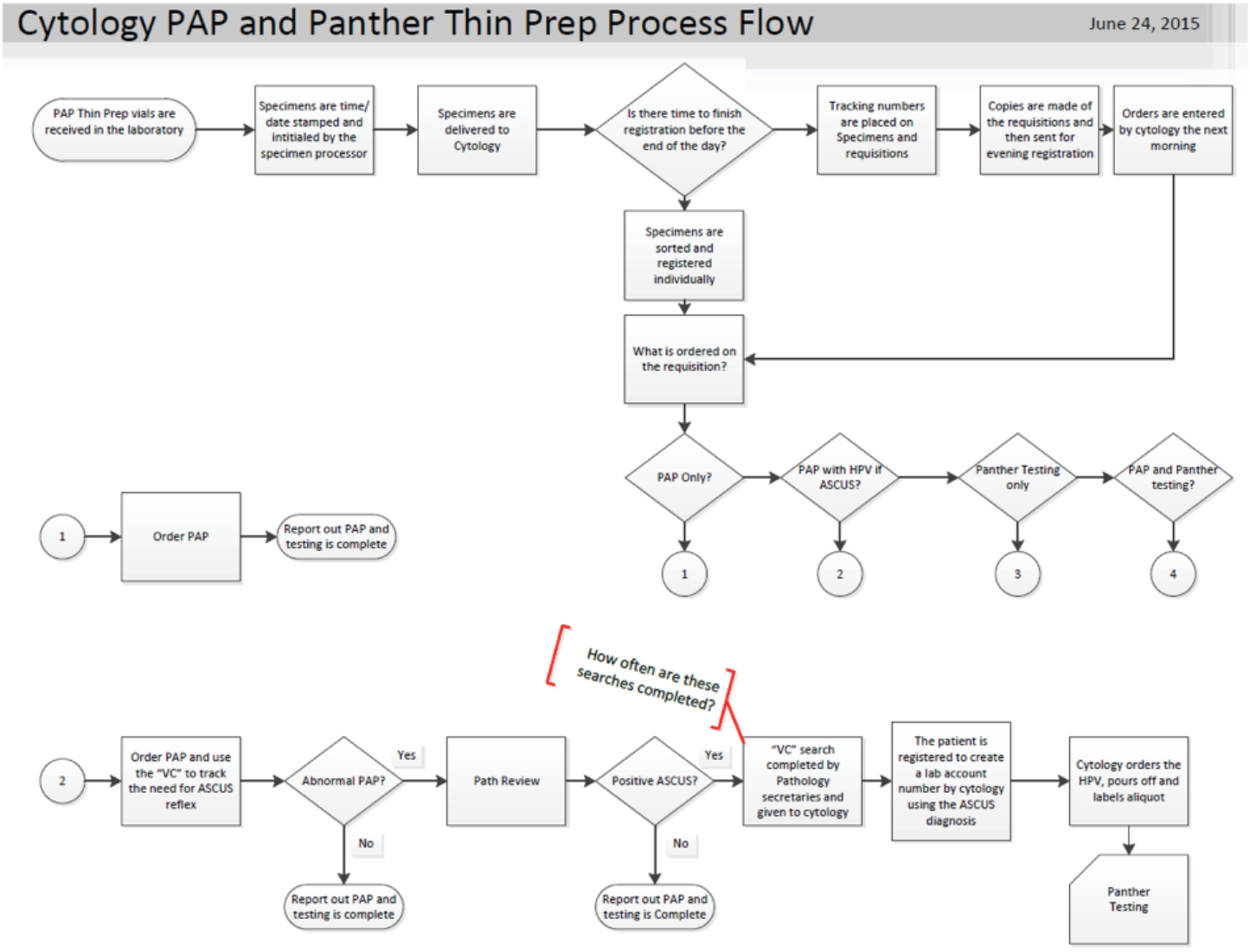
CORE PROCESSES	
Pre-analytic	Test Ordering
	Specimen
	• Collection
	• Transport
	• Receipt/Accessioning
Analytic	Hematology
	Chemistry
	Special Chemistry
	Microbiology
	Immunology
	Blood Bank
	Flow Cytometry
	Anatomic Pathology
Post-analytic	Patient Reports
	Specimen Storage

SUPPORT PROCESSES
Client Services
Review of service agreements
Document control
Referral laboratories
External services and supplies
Advisory services
Resolution of complaints
Corrective action
Preventive action
Continual improvement
Evaluation and audits
Management review
LIS
Safety
Temperature sensing

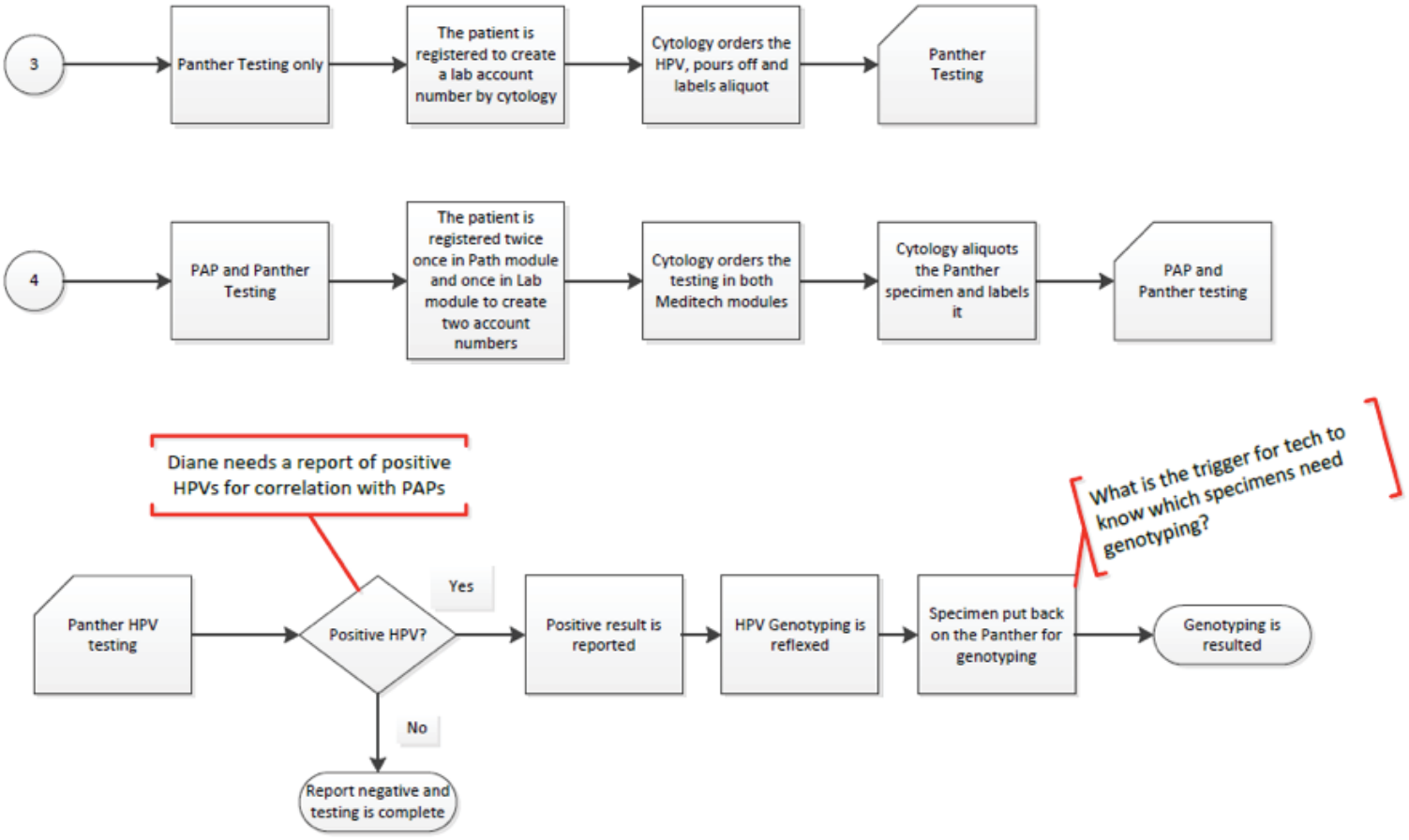
Appendix C—Example of Risk Assessment for a New/Planned Process

Note: The example beginning on the next page is from Blanchard Valley Health System in Findlay, Ohio. The quality team developed the flow charts to assess and reduce the risks of a new Panther Instrumentation platform for Pap smears. The key risks were contamination and lack of timeliness.

Appendix C (continued)



Appendix C (continued)—Cytology PAP and Panther Thin Prep Process Flow



Appendix D—Example of Initial FMEA Risk Assessment Document for Specimen Collection Process

1. Process Map

2. Risk Points / Failure Modes (see below)
3. Assessments of probability and severity/impact (see below)
4. Actions taken or planned to mitigate risks (see below)

Processes and Sub-processes	Risk points/ Failure modes	Causes	Effects	Severity/ Impact*	Probability**	Actions taken to reduce failure mode
1. Receive Order	1a. Incorrect Order	Doctor mix up of patient charts Writing is illegible	Incorrect patient is drawn → Incorrect treatment	4-5	H	Consider implementing electronic order-ing Encourage physician culture of attentiveness (eg, through Grand Rounds program)
	1b. Timing incorrect	Peak and trough mix up	Can't see effect of meds → Delay of effective treatment → Necessary to redraw the trough and peak→ Increased length of stay	3	H	Consider bar code wanding system to alert for order timings

* 1 = Marginal, 2 = Significant, 3 = Serious, 4 = Very Serious, 5 = Catastrophic
** L = Low, M = Medium, H= High

5. Process monitoring data and plans for follow up

   Note: The assessment team would look at the documentation for quality metrics, occurrence management, internal audits, management reviews, and periodic review of processes.

Appendix E—IQCP Section 1 (Risk Assessment) Example

Note: The following is a sample risk assessment for a glucose test.

Test: Glucose

RISK CATEGORY	POTENTIAL SOURCES OF ERROR	WAYS OF REDUCING THE CHANCE OF ERROR
Specimen		
Patient prep	Fasting and blood sugar—collection after a person has eaten breakfast	Breakfast served at 8:00 AM: don't collect glucose samples after 8:00 AM.
Specimen collection	Proper collection tube not used	Collection tube without preservative should be sent to lab immediately for separation of serum from blood cells.
Specimen labeling	Nurse or phlebotomist puts wrong information on tube	No pre-labeling allowed Bedside labeling only.
Specimen storage, preservation, and stability	Specimen stored too long at room temperature	Separate serum from blood appropriately, at correct temperature.
Test System		
Expired calibration	Analysis yielded erroneous result due to expired calibration.	Adhere to calibration schedule. Purchase instrumentation that does not allow testing with expired calibration curves.
Incorrect delivery of sample volume	Delivery of too much sample volume into instrument reaction vessel.	Perform required maintenance at proper intervals, which includes replacing syringes/tips.
Reagent		
Expired reagents	Low reactivity of reagents, thus decreasing accuracy of analysis.	Purchase instrumentation that does not allow testing with expired reagents on-board. Develop a reagent inventory control system that identifies and removes expired reagents from use.
Reagents not stored properly	Low reactivity of reagents, thus decreasing accuracy of analysis.	Store reagents within specified temperature and light requirements. Monitor daily. Use an electronic, continuous temperature monitoring system. Take actions to correct "out-of-range" temperatures.

RISK CATEGORY	POTENTIAL SOURCES OF ERROR	WAYS OF REDUCING THE CHANCE OF ERROR
Environment		
Specimens dropped/spilled	Non-ergonomic design of laboratory with obstructions to workflow.	Plan workflow. Design with space and expansion for the future.
Testing Personnel		
Untrained staff	Staff not knowledgeable about analysis performance.	Perform competency assessments that are "eyes-on" and not review of procedure.
Increased staff turnover	Staff not being properly trained.	Develop procedures that accommodate ongoing changes in staff. Simplify and reduce individual judgments.

Note: The next step for the laboratory would be to document action steps taken to implement the various mitigation strategies.
For example, what SOP's did they revise to mitigate the specific risks identified?