BIOGENIX

POLICY PROCEDURE FOR RISK ASSESMENT

	NAME	DESIGNATION	SIGNATURE	DATE
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1. TABLE OF CONTENT

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4. POLICY STATEMENT

The Risk assessment in BIOGENIX laboratory is done as per this procedure.

5. PURPOSE

Risk management activities in the Laboratory includes identifying the risk, investigating, analyzing & evaluating risks followed by corrective /preventive action plans and regular monitoring which reduces, manages, & eliminating risk. To analyze a process to see where it is likely to fail & see how changes you are considering might affect the safety of the process. It's an effort to reduce & assess risks to patients, staff & organization with in the centre and avoid system failure.
As per ISO 15189: 2012 Medical Laboratory –Requirements for quality and competence.
clause no. 4.14.6 Risk management: *"To evaluate the impact of work process and potential failure on examination results as they affect patient safety".*

Some Sources of risks:

5.1 Communication Process
5.2 Knowledge of competency of test operators;
5.3 Management commitment
5.4 Outside influences
5.5 Resources
5.6 Technical components
5.7 Process / Procedures
5.8 Financial-decision based on cost quality

For that BIOGENIX laboratory adopt a proactive approach to risk management.

6. SCOPE

6.1 This procedure is applicable to all kinds of risks in the laboratory.
6.2 Target Audience
6.2.1 BIOGENIX Management
6.2.2 BIOGENIX Staff

7. DEFINITIONS

7.1. **Risk:** A probability or threat of damage, injury, liability, loss or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through preemptive action.

8. ACRONYMS

N.A.

9. RESPONSIBILITIES

9.1. Everyone in the laboratory is responsible to identify and report risk.

9.2. Safety Manager and Quality Manager is responsible to do risk analysis and evaluation and initiate for risk control to the management if required.

9.3. The laboratory director is responsible to take action and control the risk.

10. PROCEDURE

10.1 Essential components of risk analysis and management plan include:

10.1.1. Risk identification

10.1.2. Risk estimation;

10.1.3. Risk evaluation;

10.1.4. Risk control;

10.1.5. Evaluation of residual risk;

10.1.6. Periodic review.

10.2. **Risk assessment**: Risk assessment is the process of identifying and evaluating the potential failures and errors that could occur during the pre-analytical, analytical and post analytical phase.

10.2.1. Evaluate the following five components of the testing process for potential failures and errors:

10.2.1.1. **Specimen:**

10.2.1.1.1. Patient preparation;

10.2.1.1.2. Specimen collection; Labeling; Storage; Preservation; Stability; Transportation;

10.2.1.1.3. Specimen registration and processing;

10.2.1.1.4. Specimen acceptability and rejection;

10.2.1.1.5. Specimen referral

10.2.1.2. **Test system:**

10.2.1.2.1. Sampling;

10.2.1.2.2. Clot detection;
10.2.1.2.3. Detection of interfering substances;
10.2.1.2.4. Calibration issues;
10.2.1.2.5. Mechanical failures;
10.2.1.2.6. Failure of system controls and function checks;
10.2.1.2.7. Software/hardware;
10.2.1.2.8. Transmission of test result.

10.2.1.3. **Reagent;**
10.2.1.3.1. Shipping/receiving;
10.2.1.3.2. Storage conditions;
10.2.1.3.3. Expiration date;
10.2.1.3.4. Preparation

10.2.1.4. **Environment:**
10.2.1.4.1. Temperature, humidity, dust, utilities;
10.2.1.4.2. Airflow/ventilation;
10.2.1.4.3. Light intensity;
10.2.1.4.4. Noise and vibration;
10.2.1.4.5. Water quality;
10.2.1.4.6. Adequate space

10.2.1.5. **Testing personnel**:
10.2.1.5.1. Education;
10.2.1.5.2. Training;
10.2.1.5.3. Competency;
10.2.1.5.4. Staffing levels.

Some risk fits under more than one of the five risk assessment components.

10.2.2. **Sources of information:**

10.2.2.1. Product insert and operator manual;
10.2.2.2. Troubleshooting guide;
10.2.2.3. Manufacturer alerts and bulletins;
10.2.2.4. Verification of performance specifications;
10.2.2.5. Personnel qualifications, training, competency;
10.2.2.6. QC and PT data;
10.2.2.7. QA information including corrective action;
10.2.2.8. Scientific publications;
10.2.2.9. Other sources as appropriate.

Note:

- A pre or post analytical failure normally affects only one patient.
- An analytical error can affect many patients at one time.

Pre Analytical	Analytical	Post Analytical
Calibration	**Consumables** (quality)	**Results: review / approve**
Calibration Verification	**Reagent dispense**	**Result Transmission**
Maintenance	**Sample dispense**	**Retrospective Review**
daily, weekly/ monthly / semi-annual		
	Reaction Chamber	**Trend Analysis**
Electrical	Temperature	
Monitoring, Surge Protection		
Dedicated Circuit	**Measurement**	
		Frequency of recalibration
Water Supply (if required)	Light source integrity	
Water quality	Clot detection	**Freq. of Device Failures**
Water integrity (air)	Interfering substances	
		Verification of Test
Humidity(mfr requirement)		**Results**
	QC approach used	**Results: review / approve**
	QC materials used	
Temp (mfr requirement)	QC frequency	**Result Transmission**
PT Performance	QC Rules	
	Patient risk	**Retrospective Review**
Calibration of small equipments	(# patients between QCs)	

Equipment		

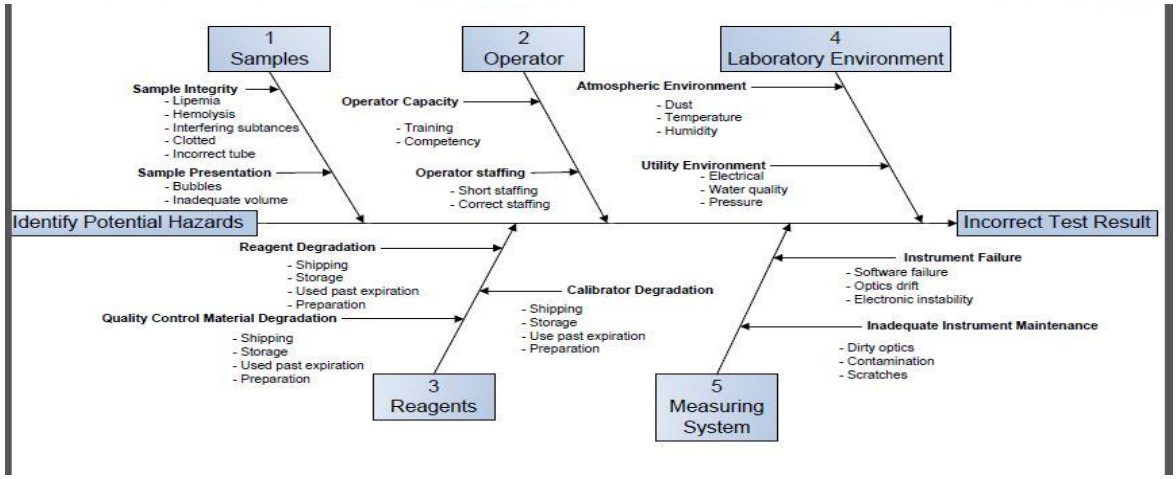
10.3. **RISK ESTIMATION:**

Tools which can be used for risk estimation:

10.3.1. Failure Mode and Effects Analysis (FMEA). Three components of FMEA are occurrence, detection and severity.

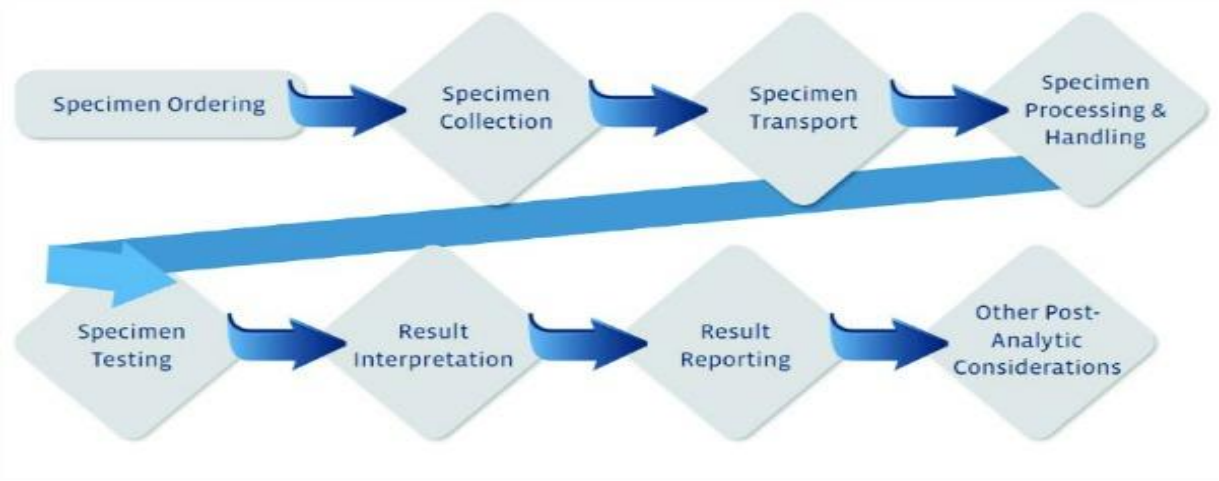
10.3.2. Each risk is assessed and a score for severity and probability is assigned on a scale of 1 to 5 with 1 being of least impact. This assessment is based on the risk in an uncontrolled system.

10.3.3. Fishbone Diagrams (more focused on a specific problem): example of using Fish bone diagram in case of incorrect test result;



10.3.4. PROCESS MAPING**:**

A process map is a graphical representation of all the steps in a testing process. This tool is used to analyze a particular testing process by breaking it down into small steps from start to finish.



10.4. **RISK EVALUATION**:

The risk score is assigned based on the following formulae (Severity x Probability) and each numerical value is equated to a qualitative interpretation of Acceptable or Unacceptable based on the clinical laboratory risk matrix table below:

		Severity					
		1 (Negligible)	2 (Minor)	3 (Serious)	4 (Critical)	5 (Catastrophic)	
Probability	1 (Improbable)	1	2	3	4	5	
	2 (Remote)	2	4	6	8	10	Acceptable
	3 (Occasional)	3	6	9	12	15	Unacceptable
	4 (Probable)	4	8	12	16	20	
	5 (Frequent)	5	10	15	20	25	

10.5. **RISK CONTROL:**

For any risk that is deemed unacceptable, the BIOGENIX laboratory identifies the ways to reduce the probability of harm, using prevention and detection methods, in order to bring the risk down to an acceptable level. This is through a variety of means such as revised operator training, posted warnings, more robust QC rules, greater surveillance of the process, or even repeat testing for values exceeding a specified threshold. In cases where the test manufacturer indicates that certain aspects of the test are monitored through built-in controls,

the lab conducts a study to verify the effectiveness of the control before including it as a control measure.

10.6. **EVALUATION OF RESIDUAL RISK:**

Once controls are assigned, the team then reviews the risks again and re-determines the risk level. Any risk not prevented or detected 100% of the time is considered residual risk. Re-estimate risk potential after mitigation (Reduction) to evaluate effectiveness.

10.7. **PERIODIC REVIEW:**

Since the goal of the risk management plan is to maintain or improve the quality, it is important to define a means to measure the quality to ensure that it meets the needs of the laboratory and the intended use of the test. Ongoing monitoring of implemented strategies to make sure they are effective in treating/reducing risk. Regular monitoring is done through KPI, keeping track and trend.

10.8. **HOW TO IMPLEMENT THE RISK MANAGEMENT PROGRAM:**

Implementation of risk management programs at all levels of the organization is a challenge for Lab staff and managers alike. The challenge for management is to support and encourage prudent risk management by:

10.8.1. Communicating and demonstrating support for risk management;
10.8.2. Define the process & outcome measures;
10.8.3. Share the results;
10.8.4. Trusting and empowering all staff to identify, analyze, report and manage risks;
10.8.5. Acknowledging, rewarding and empowering good risk management practices;
10.8.6. Ongoing identification and management of systemic problems and their causative/contributory factors and treating them appropriately;
10.8.7. Encouraging the staff to report near misses;
10.8.8. Developing appropriate risk treatment strategies to reduce the likelihood or recurrence of the problem and/or consequences; and
10.8.9. Ongoing monitoring of implemented strategies to make sure they are effective in treating/reducing risk;

10.9. **EXPECTED OUTCOMES:**

10.9.1. To identify the risk and prevent the incidence;
10.9.2. Lesson learned for each risk and how to make continue improvement in the services.

10.10. **REPORTING STRUCTURE:**

10.10.1. The staff reports to Safety Manager or quality Manager;
10.10.2. Report is documented and discuss with laboratory director.
10.10.3. Laboratory Director decides the time frame and what actions to be taken.

11. CROSS REFERENCE

11.1. HAAD standard for clinical Laboratory

11.2. ISO 15189:2012 Medical Laboratories –Requirement for Quality and Competence

11.3. Clinical Laboratory Improvement Amendments, Subpart A, Section 493.1 Basis and scope. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-part493.pdf. Accessed January 25, 2015;

11.4. http://www.clpmag.com/2015/02/risk-assessment-clinical-labs/#sthash.z5zFW6wr.dpuf

11.5. http://qcnet.com/iqcp/_/pdf/iqcp3_iqcp-performing-a-risk-assessment.pdf;

12. RELEVANT DOCUMENTS & RECORDS

12.1. BG/REC/GEN/056 Risk Assessment Work Sheet

12.2. BG/REC/GEN/057 Risk Registry