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1.0 Objective

- To ensure that risks and opportunities are identified, treatment planned to minimize their impact and how opportunities are managed to improve their likelihood and benefit.

2.0 Scope


- This documented procedure covers all the procedures starting from the identification of the risk or opportunity up to the rating of the risk/opportunity after the risk treatment had been applied.

3.0 Definition of Terms:

- **Risk:** A negative effect of uncertainty.
- **Opportunity:** A positive effective of uncertainty.
- **Uncertainty:** A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)
- **Risk Assessment:** a systematic investigation and analysis of potential risks, combined with the assignment of severities of probabilities and consequences. These are used to rate risks in order to prioritize the mitigation of high risks.
- **Risk Mitigation:** a plan developed with the intent of addressing all known or possible risks and preventing their occurrence.
- **FMEA (Failure Mode Effects Analysis):** a specific risk method for identifying risks and ranks risks by probability and consequence.
- **PPA (Potential Problem Analysis):** a specific risk method for identifying risks and rank risks by probability and consequence
- **Detection:** Additional controls or feedback mechanisms that can result in a reduction of either the severity or probability (or both).
- **Risk Priority Number (RPN):** Composite risk score of severity x probability x detectability; relative priority for taking action- the bigger the RPN, the more important to address failure being assessed.

4.0 Records

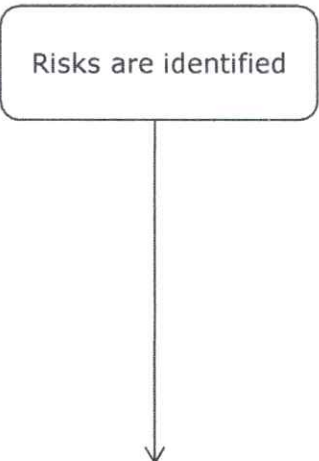
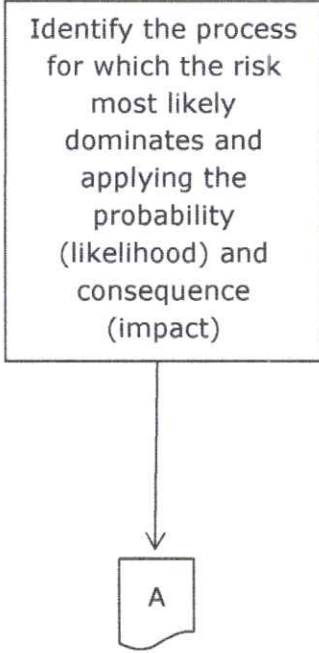
- PL BAI-08 Risk Register (FMEA)
- PL BAI-09 Risk Register (PPA)
- PL BAI-10 Opportunity Register

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5.0 References

- ED BAI-01 PNS ISO 9001:2015 Quality Management Systems Requirements
- ED BAI-02 PNS ISO 9000:2005, Quality Management Systems – Fundamentals and Vocabulary
- ED BAI-03 PNS ISO IEC 17020:2012 Inspection Body Requirements

6.0 Management of Risk Process

FLOW	RESPONSIBILITY	INTERFACE/DETAILS
	QMS Core Team member/ Process owner/employee	<ul style="list-style-type: none"> • Use GF BAI-97 and 98 Risk Register Templates • Additional risks may be identified by any employee at any time • Each process is defined in detail through the Risk Templates. • This document includes the identification and mitigation plans for key risks associated with the defined process. The Top Management reviews these risks and takes actions to minimize them.
	QMS Core Team member/ Process owner/employee	<p><i>When <u>Potential Problem Analysis (PPA)</u> style risk treatment is used</i></p> <ul style="list-style-type: none"> • Assigning a <u>probability</u> rating to the identified risk; this probability is comprised of two elements: likelihood and previous occurrences. Each element is given a score from 1 (lowest risk) to 5 (highest risk). The final probability rating is the average of the elements • Assigning a <u>consequence</u> rating if the risk were to be encountered; this consequence is comprised of five elements as described in Table 1. Again, each element is



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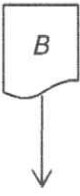
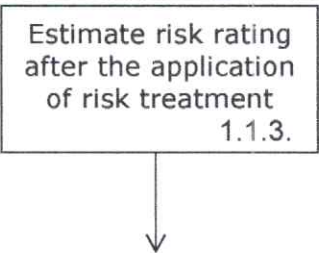
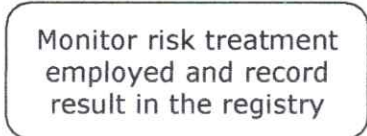
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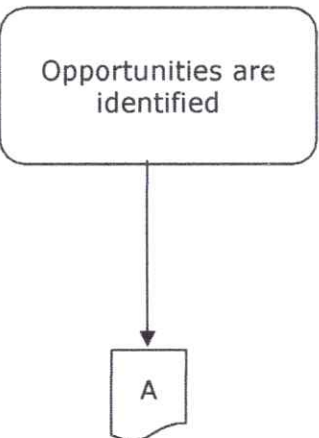
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<p style="text-align: center;">A</p> <p style="text-align: center;">↓</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p>Calculate the Risk Rating base on the equation: PROBABILITY RATING x CONSEQUENCE RATING = RISK RATING</p> </div>		<p>given a score from 1 (lowest risk) to 5 (highest risk). The final consequence rating is the average of the elements. See Table 1 below.</p> <ul style="list-style-type: none"> • <i>Actions required for Risk Ratings are reflected in Table 2</i> • <i>Risk with a risk rating of low may be accepted without a mitigation plan, unless otherwise directed by management</i>
<div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p>Calculate the Risk Rating base on the equation: PROBABILITY RATING x CONSEQUENCE RATING x DETECTABILITY = RISK PRIORITY NUMBERR</p> </div> <p style="text-align: center;">↓</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p style="text-align: center;">B</p> <p style="text-align: center;">↓</p> </div>	<p style="text-align: center;"><i>QMS Core Team member/ Process owner/employee</i></p>	<p><i>When Failure Mode Effects Analysis (FMEA) style risk treatment is used</i></p> <ul style="list-style-type: none"> • <i>Assigning a <u>probability</u> rating to the identified risk; this probability is comprised of two elements: likelihood and previous occurrences. Each element is given a score from 1 (lowest risk) to 5 (highest risk). The final probability rating is the average of the elements</i> • <i>Assigning a <u>consequence</u> rating if the risk were to be encountered; this consequence is comprised of five elements as described in Table 1. Again, each element is given a score from 1 (lowest risk) to 5 (highest risk). The final consequence rating is the average of the elements. See Table 1 below.</i> • <i>Assigning detection level for the risk identified which is comprised of 5 elements as described in Table 3. Again, each element is given a score from 1 (can be detected immediately) to 5 (cannot be detected)</i>

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		<ul style="list-style-type: none"> For risks with RPN that is > than 49 will be prioritized for mitigation or rejection. See Table 4. The mitigation plan must be documented, either in the Risk Register (PL BAI-08) or in another document which must be referenced on the form GF BAI-97 Risk Registry Form.
	QMS Core Team member/ Process owner/employee	<ul style="list-style-type: none"> The final column allows for entry of an estimated risk factor after mitigation, which is an estimate on what the risk should be reduced to if the risk treatment is successful.
	QMS Core Team member/ Process owner/employee	<ul style="list-style-type: none"> Refer to Risk Register (PL BAI-08 and 09)

Management of Opportunity Process

FLOW	RESPONSIBILITY	INTERFACE/DETAILS
	QMS Core Team member/ Process owner/employee	<ul style="list-style-type: none"> Use PL BAI-10 Opportunity List Actively seek out opportunities which could enhance our resources and manpower competence. For example- international sponsored training, international funding agencies for livestock projects, etc. Opportunities are identified in the Context of the Organization (QM 4.1)



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<div style="text-align: center;"> <p>A</p> <p>↓</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">Discuss and analyze opportunities</div> <p>↓</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p>Calculate the Risk Rating base on the equation:</p> <p style="text-align: center;">PROBABILITY RATING x OPPORTUNITY RATING = OPPORTUNITY RATING</p> </div> <p>↓</p> </div>	<p style="text-align: center;">Top Management/ QMS Core Team</p>	<ul style="list-style-type: none"> • Discussing and analyzing opportunities shall be done by top management. If made part of the management review activities, these shall be recorded in the management review records. • Assigning a probability rating to the identified opportunity; this probability that the organization can achieve the opportunity. It is comprised of two elements: likelihood and previous occurrences. Each element is given a score from 1 (lowest probability) to 5 (highest probability). • Assigning a benefit rating to assess potential benefits if the opportunity is won. This is comprised of five elements: potential for additional resources; potential for collaborative work; potential improvements in the organization's ability to satisfy regulatory or statutory requirements; potential improvements to the quality management system; and potential enhancements of BAI's reputation. Again, each element is given a score from 1 (lowest benefit) to 5 (highest benefit). • See Table 2 below.
<div style="text-align: center;"> <p>B</p> </div>	<p style="text-align: center;">QMS Core Team</p>	<ul style="list-style-type: none"> • For opportunities with a final Opportunity Factor rating equal to or greater than the threshold set in the Opportunity Register, management will decide whether to pursue the opportunity through an



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		<p>"opportunity pursuit plan" or to abandon the opportunity altogether.</p> <ul style="list-style-type: none"> • The opportunity pursuit plan must be documented, either in the Opportunity Register or in another document which must be referenced on the form. • Opportunities with a factor less than the opportunity target rating may be abandoned outright, unless otherwise directed by top management.
	<p>QMS Core Team</p>	<ul style="list-style-type: none"> • The final column allows for entry of success result, once the opportunity has been closed; this includes entries for abandoning the opportunity, and failing to win the opportunity. • Pursue the opportunity • Explore the opportunity in greater detail before proceeding • Accept the opportunity, but under limited and controlled conditions • Decline the opportunity, typically based on a high expected cost or low anticipated benefit • If an opportunity includes a negative aspect, management may elect to conduct a risk assessment on the negative aspect, as defined above.
	<p>QMS Core Team</p>	<ul style="list-style-type: none"> • Update opportunity listing as necessary



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Table 1. Evaluating Risk Likelihood and Consequence Matrix

	Likelihood of Occurrence	Consequence if Event Occurs				
		Insignificant (Negligible) 1	Minor (Low) 2	Moderate (Medium) 3	Major (High) 4	Catastrophic (Extreme) 5
		<ul style="list-style-type: none"> <5% below target ≤ 5 days delay No customer complaint 	<ul style="list-style-type: none"> 5-10% below target ≥ 5 days delay Minor customer complaint 	<ul style="list-style-type: none"> 11-20% below target 2 or more customer complaints 	<ul style="list-style-type: none"> 21-30% below target Legal action on complaints Product recall Options available 	<ul style="list-style-type: none"> > 30% below target Lawsuit on complaints Product recall Options not available
5	Known to happen more than 1x/quarter/every month (Expected)	5	10	15	20	25
4	Known to happen more than 1x/quarter (High)	4	8	12	16	20
3	Known to happen up to 1x/quarter (Medium)	3	6	9	12	15
2	Known to happen once a year (Likely)	2	4	6	8	10
1	Not known to happen (Unlikely)	1	2	3	4	5



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Table 2. Risk Evaluation and Action Priority

RISK RATING	RISK PRIORITY	ACTION REQUIRED
EXTREME RISK (15-25)	P1	Unacceptable Risk: Priority action, budget to be approved within the next 3 months, add additional controls, review adequacy of current controls
HIGH RISK (10-12)	P2	Unacceptable Risk: Action to be second priority, add additional controls, review adequacy of current controls
MODERATE RISK (4-9)	P3	Investigate further risk controls; Action to be done if there are available resources
LOW RISK (1-3)	P4	Risk is acceptable: No further risk controls required, to be noted



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Table 3. Detection Table

Value	Description	Criteria
1	High degree of detection	Presence of two or more automatic or manual detection systems; visible reaction
2	Good detection	Manual detection that is a direct measure of failure
3	Likely to detect	Presence of detection system that is not a direct measure of failure
4	Fair detectability	Visual level check
5	No detectability	Not able to detect the failure

Table 4. Risk Acceptability based on RPN

Priority Ranking	Actions Required
1 > 49 RPN	Unacceptable Risk: Priority action, budget to be approved within the next 3 months, add additional control, review adequacy of current controls; Justification required for risk that is accepted
2 30-49 RPN	Unacceptable Risk: Action to be second priority, add additional controls, review adequacy of current control; Acceptable only if it cannot be further mitigated by organizational or technological solutions
3 15-29 RPN	Tolerable: Risks should be periodically reviewed for reduction; Action to be done if there are available resources
4 1-14 RPN	Risks is acceptable: No further risk controls required, to be noted



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Table 3. Evaluation of Opportunity Likelihood and Consequence

Likelihood of Occurrence	Consequence if Event Occurs				
	Very Low 1	Low 2	Medium 3	High 4	Very High 5
5 >75% chance of success within the next 12-24 months with existing condition	• No perceived value for improvement	• Pursuing the opportunity will slightly improve good governance	• Pursuing the opportunity will considerably improve good governance	• Pursuing the opportunity will highly improve good governance	• Pursuing the opportunity will greatly improve good governance essential for sustainability
4 51-75% chance of success within the next 12-24 months with existing condition	5	10	15	20	25
3 26-50% chance of success within the next 12-24 months with existing condition	4	8	12	16	20
2 1-25% chance of success within the next 12-24 months with existing condition	3	6	9	12	15
1 No chance of success within the next 12-24 months with existing condition	2	4	6	8	10
1 No chance of success within the next 12-24 months with existing condition	1	2	3	4	5


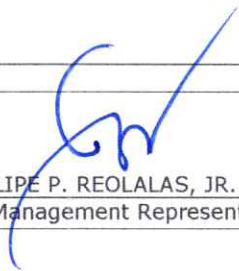
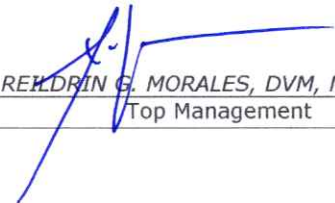
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Table 6. Action Priority for Opportunities

Opportunity Rating	Priority Level	Action Required
High	P1	Pursue the opportunity
Moderate	P2	Explore the opportunity
Low	P3	Accept the opportunity, but under limited and controlled conditions
Very Low	P4	Decline the opportunity, typically based on a high expected cost or low anticipated benefit

Prepared by:	Approved by:
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