
	<b>UNIVERSITI KUALA LUMPUR</b> <b>ROYAL COLLEGE OF MEDICINE PERAK</b>  <b>RISK &amp; OPPORTUNITIES ASSESSMENT</b>	Doc. No:	UniKL/RCMP/ QMS-06
		Revision No:	00
		Date	01 July 2017
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#### AMENDMENT RECORDS

No.	Date	Remarks	Revision No.	Approved by
1	01 July 2017	• Establishment	00	QMR

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## 1.0 PURPOSE

To understand the organization and its context, the needs and expectations of interested parties, so as to determine the risks and opportunities, and address the actions to achieve the intended results of its QMS.

## 2.0 SCOPE

This procedure applies to determine the external and internal issues, and needs and expectations of interested parties, determine the risks and opportunities, identify the effect and current actions addressed, assess its effect and possibility level by priority no., address the additional action required, until the evaluation of the effectiveness of action taken.

## 3.0 RESPONSIBILITY AND AUTHORITY

Top Management / QMR shall be responsible to facilitate the assessment session, monitor and evaluate the effectiveness of action taken. Management Team shall be responsible to prepare and contribute ideas during these exercises, take actions on their responsible areas, and monitor until the intended results are achieved.

## 4.0 REFERENCE

Clause 4.1 : Understanding the organization and its context

Clause 4.2 : Understanding the needs and expectations of interested parties

Clause 6.1 : Actions to address risks and opportunities


Clause 6.3 : Plannig of Changes

## 5.0 RECORDS

Please refer to the relevant records as per Record Master List.

## 6.0 FORM

Please refer to the relevant forms as per Document Master List (Form).

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## 7.0 RECORDS

No	Titles/Records	Reference Number	Location	Retention Period
1	ROA Form	UniKL/RCMP/QMS-06-01	Main Office	3 YEARS



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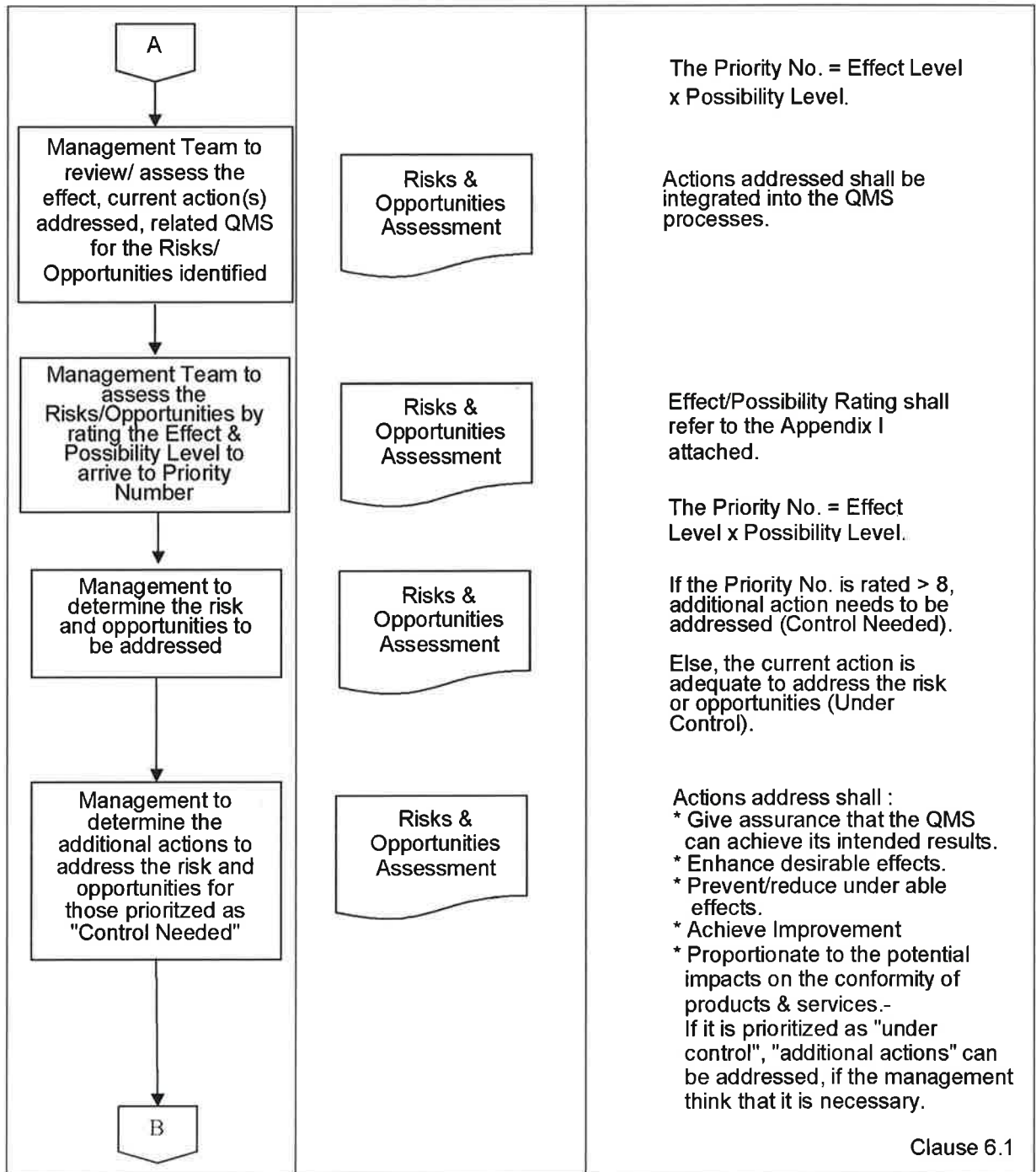
PROCESS	RECORD	DESCRIPTION
<pre> graph TD     Start([Start]) --&gt; QMR[QMR to facilitate the Management Team to understand &amp; determine External &amp; Internal Issues, and Needs &amp; Expectation of Interested Parties, then link it to either Risks or Opportunities]     QMR --&gt; A{{A}}           </pre>		<p>The issues shall be relevant to its purpose (i.e. related to the product &amp; services provided) and its strategic direction, and affect its ability to achieve the intended results of its QMS, such as meeting customer requirements, or enhance customer satisfaction.</p> <p>The External Issues can be facilitated through market, competitiveness, legal, economics, culture/social, and technological. The Internal Issues shall be facilitated by respective Depts. and to consider the values, culture, knowledge and performance of organization.</p> <p style="text-align: right;">Clause 4.1</p> <p>The needs &amp; expectations of interested parties &amp; its requirements shall be determined.</p> <p>The interested parties refer to customer, suppliers and statutory body that are relevant to the QMS only. The requirements refer to quality related requirements only.</p> <p style="text-align: right;">Clause 4.2</p>



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<p style="text-align: center;">B</p> <p>QMR to monitor the Incharge Person to carry out the Actions in a planned manner as per its deadline.</p> <p>QMR to monitor, review &amp; evaluate the effectiveness of additional actions taken.</p>	<p style="text-align: center;">Risks &amp; Opportunities Assessment</p> <p style="text-align: center;">Risks &amp; Opportunities Assessment</p>	<p>While carrying out the plan, the management shall consider :</p> <ul style="list-style-type: none"> <li>* the purpose of the changes and their potential consequences</li> <li>* the integrity of the QMS</li> <li>* the availability of resources</li> <li>* the allocation or reallocation of responsibility and authorities.</li> </ul> <p style="text-align: right;">Clause 6.3</p> <p>QMR to monitor on quarterly basis, and review to evaluate its effectiveness during management review meeting by providing proof of action taken.</p> <p>The re-assessment shall be reviewed and conducted once a year.</p>
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**(A) RATING FOR EFFECT LEVEL**

<b>LEVEL</b>	<b>RISKS</b>	<b>OPPORTUNITIES</b>
<b>1</b>	No Effect	Not Helpful
<b>2</b>	Fair	Slightly Helpful
<b>3</b>	Fairly High	Helpful
<b>4</b>	High	Very Helpful

**NOTE :**

1. Effect on Risk refers to the Risk Effect to the impact to achieve the intended results of QMS.
2. Effect on Opportunity refers to how helpful the opportunities to enhance customer satisfaction or give positive impact to the company.

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**(B) RATING FOR POSSIBILITY LEVEL**

<b>LEVEL</b>	<b>RISKS</b>	<b>OPPORTUNITIES</b>
<b>1</b>	Not Possible	Not Possible
<b>2</b>	Possible	Possible
<b>3</b>	Fairly Possible	Fairly Possible
<b>4</b>	Highly Possible	Highly Possible

**NOTE :**

1. Possibility on Risk refers to how possible the Risk may happen and impacts the achievement of the intended results of QMS.
2. Possibility on Opportunity refers to how possible the company can gain or use the Current Action to gain/capitalize the Opportunities identified.