


	<b>UNIVERSITI KUALA LUMPUR ROYAL COLLEGE OF MEDICINE PERAK</b>  <b>INTERNAL QUALITY AUDIT</b>	Doc. No:	UniKL/RCMP/ QMS-03
		Revision No:	01
		Date	01 July 2017
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<p>Prepared by:</p> <p style="text-align: center;"></p> <p>Name : Nur Iman Binti Abdul Wahab Position : Document Officer  Date : 22 June 2017</p>	<p>Approved by:</p> <p style="text-align: center;"></p> <p>Name : Thian Yee Wei Position: Quality Management Representative (QMR)  Date : 22 June 2017</p>
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**AMENDMENT RECORDS**

No.	Date	Remarks	Revision No.	Approved by
1	09 May 2014	Establishment	00	QMR
2	01 July 2017	Upgrading of ISO 9001:2015 (Refer to the items highlighted in blue)	01	QMR

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## 1. OBJECTIVE

This procedure defines responsibility, methods and requirements in conducting a quality audit to verify the effectiveness of the implementation of Quality Management System to the organization's quality system and ISO 9001: 2015 requirements.

## 2. SCOPE

The scope of this procedure is activities at UniKL RCMP.

## 3. REFERENCE

NIL


## 4. DEFINITION

**QMS** : Quality Management System is a management system on the basis of MS ISO 9001:2015 Quality benchmarking.

**QMR** : Quality Management Representative who is responsible for effective implementation of MS ISO 9001:2015 Quality Management System.


**HOD** : Head of Department

**HOP** : Head of Program

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## 5. PROCEDURES

- 5.1 The QMR will prepare an internal quality Audit Schedule [UniKL/RCMP/QMS-03-01](#), in which he will specify the month and days of each activity listed to be audited.
- 5.2 The QMR will determine how frequently the element will be audited, but the audit interval between any elements will not exceed 12 months.
- 5.3 The audit program will be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits.
- 5.4 The QMR will first agree with the relevant HOD/HOP's suggestion of an appropriate date for the audit to take place within the scheduled month. Where it is not convenient for either party to arrange the audit within the specified month, the audit will then be rescheduled by QMR.
- 5.5 The entire element within the quality system will be audited by the internal auditors according to the Audit Checklist - [UniKL/RCMP/QMS-03-02](#) prepared by auditors. The auditors are considered a qualified auditor once they have completed the internal quality audit course conducted by a certified agency.
- 5.6 Once the auditors have completed the audit activities, they will record the findings in the Audit Report and any non-conformance observed will be recorded in the Corrective Action Request form - [UniKL/RCMP/QMS-03-03](#) and Audit Report. Where the corrective action involves change in any quality system, the change will be carried out in accordance with Document Control procedure and any other form of corrective action which will be coordinated by the QMR and implemented by relevant personnel.
- 5.7 The custodian responsible for the area being audited shall take prompt action to eliminate detected non-conformities and their causes. The completion due date will be highlighted in the Corrective Action Request form - [UniKL/RCMP/QMS-03-03](#).

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- 5.8 The QMR will ensure that where follow-up audit activities are carried out, the action proposed has been fully implemented and is effective.
- 5.9 The general findings of any audit will be reviewed at the management review as part of the efficiency review.
- 5.10 A non-conformance should be recorded if there are evidences of non-fulfilment of specified requirements. They are raised in the event of :
- a) Not meeting a specific clause of MS ISO 9001:2008 standard.
  - b) Not meeting a part of a quality system procedure or work instruction.
  - c) Not meeting customer's requirements.
- 5.11 The details of corrective action request (CAR) will be normally classified into two categories, major or minor.
- a) Major non-conformance, reflects a serious breakdown of the quality management system. Major non-conformance means that part of the system or entire system is not effective.
  - b) Minor non-conformance, lapses in the quality management system which means that the overall quality system is functioning but there are isolated cases of non-conformance. If there is a significant number of them, they can collectively constitute to a major non-conformance.
- 5.12 Observation remarks will be followed with recommendation (if necessary) by the auditors. However, the above observations are not mandatory and subject to quality system failure.

## 6. RECORDS

Record Ref.	Record Name	Retention Period
<a href="#">UniKL/RCMP/QMS-03-01</a>	Audit Schedule	3 Years
<a href="#">UniKL/RCMP/QMS-03-02</a>	Audit Checklist	3 Years
<a href="#">UniKL/RCMP/QMS-03-03</a>	Corrective Action Request	3 Years



**UNIVERSITI KUALA LUMPUR  
ROYAL COLLEGE OF MEDICINE PERAK  
AUDIT SCHEDULE**

Doc. No:	UniKL/RCMP/ QMS-03-01
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**INTERNAL QUALITY AUDIT AND MANAGEMENT REVIEW MEETING SCHEDULE**

YEAR : 2017 - 2019

ACTIVITY	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEP	OCT	NOV	DEC
INTERNAL QUALITY AUDIT	PLAN											
	ACT											
MANAGEMENT REVIEW MEETING	PLAN											
	ACT											

PREPARED BY	APPROVED BY
Name : Quality Management Representative Date :	Name : Chief Executive Officer Date :



**UNIVERSITI KUALA LUMPUR  
ROYAL COLLEGE OF MEDICINE PERAK  
AUDIT CHECKLIST**

Doc. No:	Unikl/RCMP/ QMS-03-02
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Procedure: \_\_\_\_\_ Procedure No. : \_\_\_\_\_

Department: \_\_\_\_\_ Date: \_\_\_\_\_

Auditor: \_\_\_\_\_ Auditee: \_\_\_\_\_

No	Questions	Records	Data	Facts	Yes	No



**UNIVERSITI KUALA LUMPUR  
ROYAL COLLEGE OF MEDICINE PERAK  
CORRECTIVE ACTION REQUEST**

Doc. No:

UniKL/RCMP/  
QMS-03-03

Revision No:

01

Date

01 July 2017

**CAR NO. :**

Department :		Auditor/Requested by :
Area / Doc. :		Auditee/Responsible by :
Details Of Non-conformity :		Issued/Requested by,  _____ )
Immediate Action :		Proposed/Acted by,  _____ )
Need action to eliminate the cause(s) of the NC ? Yes / No		
Results of Investigation :		Investigated by,  _____ )
Corrective Action/Countermeasure: (Action to prevent from reoccur)		Proposed/Acted by,  _____ )
Need to change the affected QMS ? Yes / No. If yes, please specify : _____ )		
Result of Corrective Action Taken :	Effectiveness of Corrective Action:	Verified by,  _____ )
Verify effective? Yes/No		
Need to update them in the next Risks & Opportunities Analysis ? Yes / No		

**Note : If verify not effective, ISSUE NEW CAR**