

22 Mac 2022

maklumat didokumentasikan

MS ISO 9001:2015



RUSIDAH MAT YATIM

Ketua Pengawal Dokumen

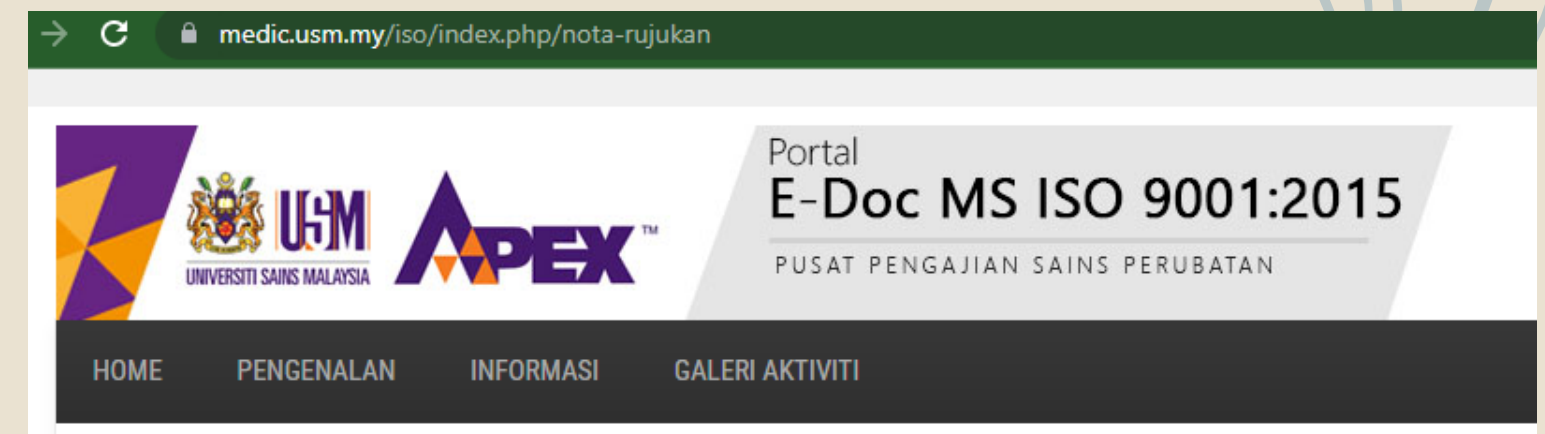
MUHAMAD FARIS IRFAN CHE YUSOFF

Timbalan Ketua Pengawal Dokumen

Start →

Our Sharing Today

KLAUSA 7.5
RUSIDAH MAT
YATIM

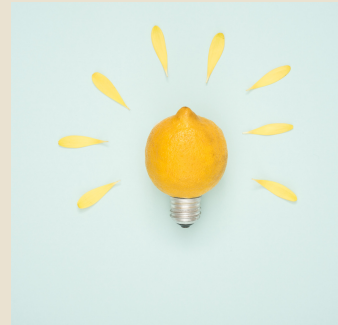


E-DOC PPSP
MUHAMAD FARIS IRFAN
BIN CHE YUSOFF



7.5.1

Am



7.5.2

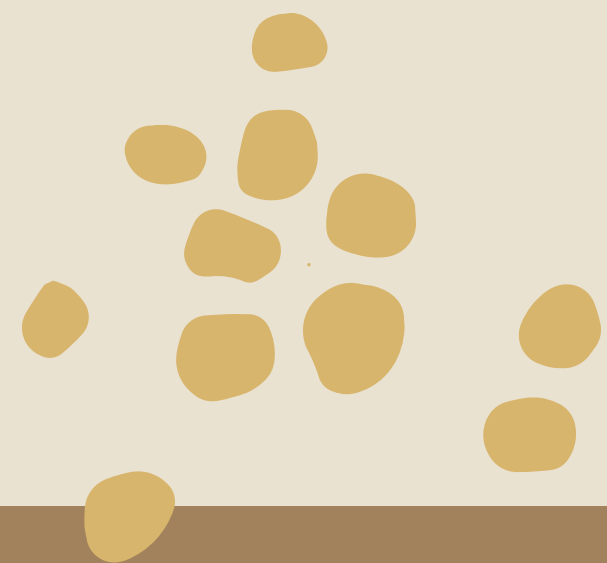
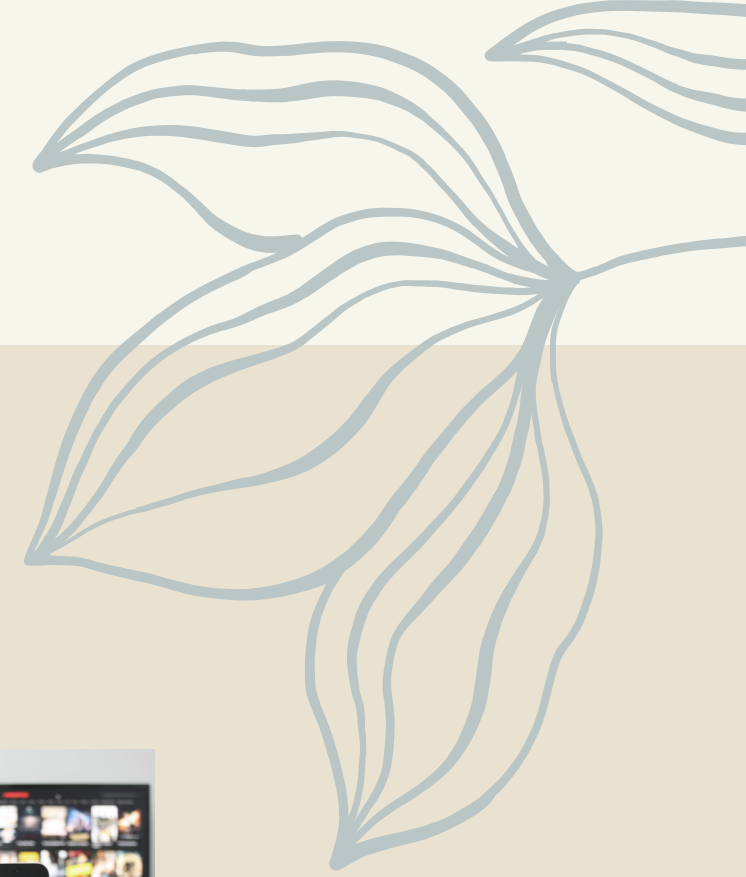
Mewujudkan dan
Mengemaskini



7.5.3

Kawalan Maklumat
Didokumentasikan

- 7.5.3.1
- 7.5.3.2

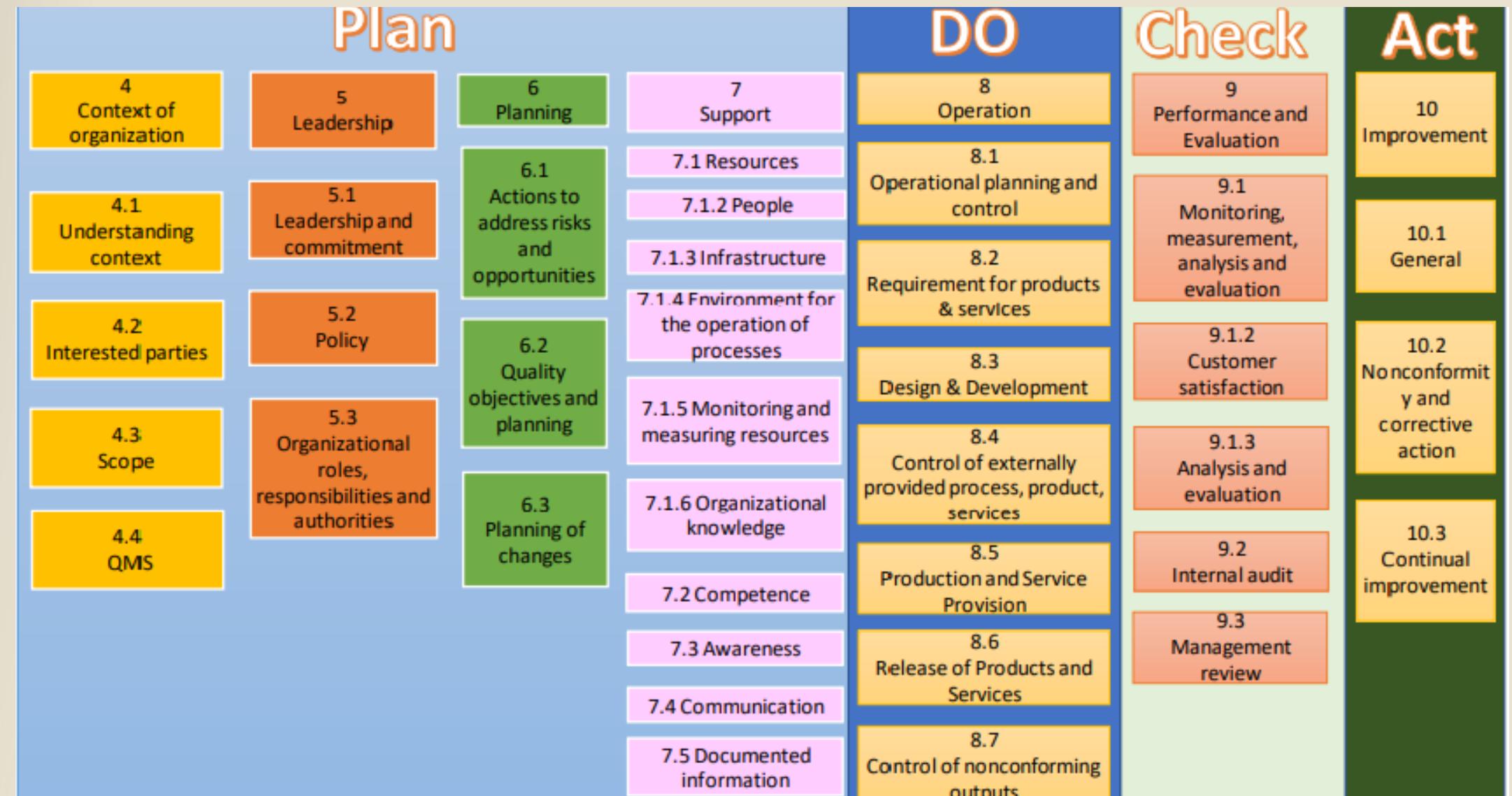


Maklumat didokumentasikan

Adalah maklumat yang digunakan untuk menerangkan semua keperluan Sistem Pengurusan Kualiti

Tahapnya berbeza antara satu organisasi dengan yang lain disebabkan oleh:

- Saiz organisasi, jenis aktiviti, proses, produk dan perkhidmatannya
- Kerumitan proses dan saling tindaknya
- Tahap kompetensi staf



Dengan izin Prof Nik Rosmawati

7.5.1 AM

STANDARD MS ISO 9001

SPK organisasi hendaklah termasuk

a) Maklumat didokumentasikan yang diperlukan oleh standard

b) Maklumat didokumentasikan yang ditentukan perlu oleh PPSP bagi keberkesanan SPK

Manual Kualiti, Prosedur wajib, borang-borang dan rekod yang berkaitan prosedur ini



7.10 Documented Information

7.10 Documented Information

PPSP shall maintain and retain the documented information to support the operations of the quality management processes are being carried out as planned.

The documented information regarding T & L includes the students' registration and attendances, timetable of the courses, process for examination and viva schedule. Students' particulars are recorded and registered as students of PPSP. This documented information are stored and maintained according to the procedure stated in the respective quality procedure. Where applicable, students obtain some experience and short courses in other medically related institution or hospitals in the country. In such cases, appropriate documented information and monitoring are followed in accordance to the set rules and regulations.

Quality records in PPSP include the student/client personal academic record, student's assessment and examination records and others including the QMS, training, survey, audit, accreditation and certification as well as purchasing and procurement.

The documented information regarding T & L

The students' registration and attendances, timetable of the courses, process for examination and viva schedule. Students' particulars training, survey, audit, accreditation and certification as well as purchasing and procurement. research grants and publications.

CP jabatan, OBE fail Kursus 6 termasuk borang-borang dan rekod yang berkaitan

QUALITY MANUAL
FOR PPSP
PPSP/QMS/QM

Klausa 7.5.2

Mewujudkan dan mengemaskini



Apabila mewujudkan dan mengemaskini maklumat didokumentasikan, organisasi hendaklah memastikan kesesuaian:

- pengenalpastian dan perihalan (tajuk, tarikh, pengarang, atau nombor rujukan);
- format (bahasa, versi perisian, grafik) dan media (kertas, elektronik);
- disemak dan diluluskan (termasuk penambahbaikan dan pindaan) dan rekodkan.



7.10

Documented information Quality Manual for PPSP

Documented information maintained are identified by a title, a unique identifier on each page, effective date of the current version and its number, amendment number, page number to total number of pages, and authorization for issue (PPSP/QMS/CD). The method of identification for documented information used in PPSP as follows: PPSP/<AcP>/<dept/unit>/CP<no> /R <serial no> for records involving academic programmes; PPSP/<dept/unit>/<activity> /R <serial no> for records involving other departmental activities. Retained documented information is managed as per procedure (PPSP/QMS/CR).

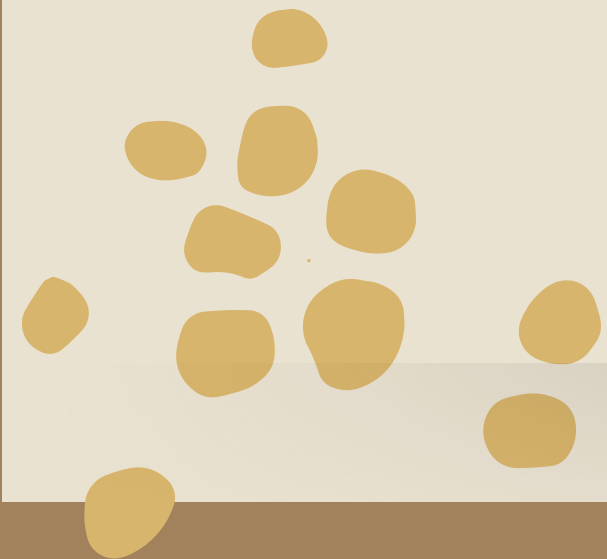
CONTROL OF DOCUMENT
(PPSP/QMS/CD)

CONTROL OF RECORD
(PPSP/QMS/CR)

Hand amendments are not allowed. All QMS documented information maintained shall be **reviewed not later than 2 years**. Responsibility of **the Document Controller** to ensure that the most current documented information maintained is issued and followed

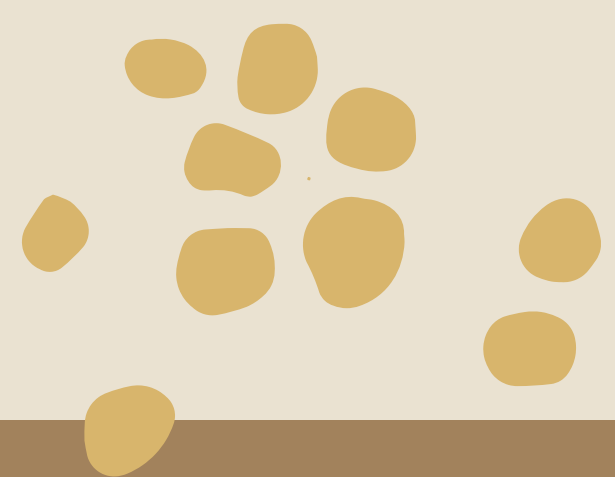
7.5.3.1 Maklumat didokumentasikan hendaklah dikawal bagi memastikan

- Ia tersedia dan sesuai untuk digunakan
- Ia dilindungi secukupnya (dari kehilangan, kerahsiaan, penggunaan yang tidak betul atau kehilangan integriti)



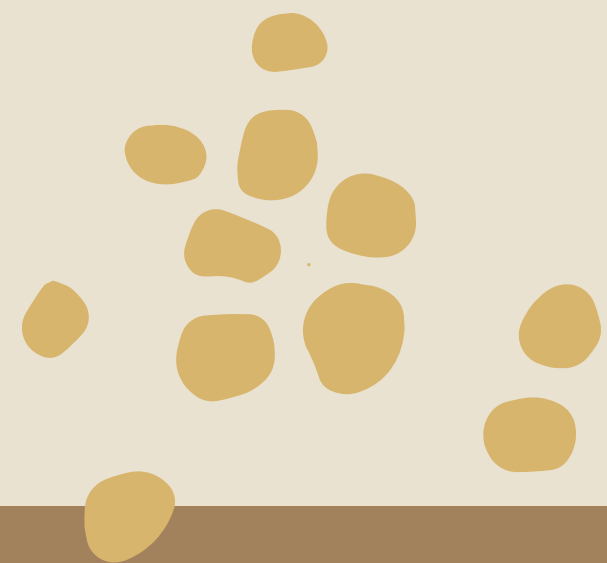
7.5.3.2: Bagi mengawal maklumat didokumentasikan, organisasi hendaklah menyatakan:-

- Bagaimana SPK dapat diakses, dimana, bagaimana dan dalam format apa?
- Penyimpanan dan pemeliharaan – bagaimana disimpan, bagaimana proses untuk melakukan pindaan, backup
- Kawalan perubahan – Kawalan edisi, rekod pindaan, penyimpanan dan pelupusan – dimana disimpan, tempoh simpanan dan kaedah pelupusan



7.5.3.2: Bagi mengawal maklumat didokumentasikan, organisasi hendaklah menyatakan:-

- Maklumat didokumentasikan yang berasal **dari luar** yang ditentukan penting dalam organisasi bagi perancangan dan operasi SPK hendaklah dikenalpasti sewajarnya dan dikawal.
- Maklumat didokumentasikan yang disimpan sebagai bukti keakuran hendaklah dilindungi daripada pengubahan tidak disengajakan.



CONTROL OF DOCUMENT PPSP

6. PROCEDURE

ACTIVITY		RESPONSIBILITY
6.1	Document Identification	
6.1.1	PPSP/QMS/ <name of document> QM for Quality manual, CD for control of document, CR for control of record, IA for internal audit, NCP for nonconforming product, CR for corrective action and PA for preventive action.	CDC/DCDC
6.1.2 Departmental core procedures (CP) involved in academic programme		
a.	PPSP/< AcP>/<dept/unit>/CP<no>	CDC/DCDC/DC
b.	PPSP/< AcP>/<dept/unit>/CP/<no> IR <serial no>for internal reference	Core Procedure: PPSP/PG/PAED/CP1
c.	PPSP/< AcP>/<dept/unit>/CP/<no> ER <serial no>for external reference.	
d.	PPSP/< AcP>/<dept/unit>/CP/<no> L/<serial no>for appendix.	
6.1.3 Departmental core procedures (CP) not involved in academic programme.		
a.	PPSP/<dept/unit>/CP<no>.	CDC/DCDC/DC
b.	PPSP/<dept/unit>/CP/<no> IR <serial no>for internal reference	Core Procedure: PPSP/Pent/CP1
c.	PPSP/<dept/unit>/CP/<no> ER <serial no>for external reference.	
d.	PPSP/< AcP>/<dept/unit>/CP/<no> L/<serial no>for appendix.	
Note: Documents already identified under other quality management systems can also be used where applicable.		

Internal Reference :
PPSP/PG/PAED/CP1/IR1

External Reference :
PPSP/PG/PAED/CP1/ER1

Appendix :
PPSP/PG/PAED/CP1/L1

5. ABBREVIATION

CDC	: Chief Document Controller
DCDC	: Deputy Chief Document Controller
DC	: Department Document Controller
CP	: Core Procedure
QM	: Quality Manual of PPSP
QMS	: Quality Management System
MR	: Management Representative
AcP	: Academic Programme
HOD	: Head of Department
PPSP	: <u>Pusat Pengajian Sains Perubatan</u>
USM	: <u>Universiti Sains Malaysia</u>
PF	: Phase coordinator
PC	: Programme Chairman
IR	: Internal Reference
ER	: External Reference
R	: Record

CONTROL OF RECORD PPSP

6. PROCEDURE

	ACTIVITY	RESPONSIBILITY
6.1	Identify method of identification	
6.1.1	PPSP/<AcP>/<dept/unit>/CP<no> /R <serial no> for records involving academic programmes.	CDC/DCDC/DC

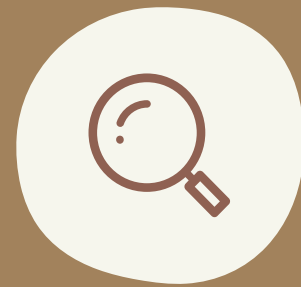
PPSP/PG/PAED/CP1/R1

6.1.2	PPSP/<dept/unit>/<activity> /R <serial no> for records involving other departmental activities.	CDC/DCDC/DC
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PPSP/Pent/UP/R1

***UP : Urusan Peperiksaan**

Penemuan 1



ACTIVITY	RESPONSIBILITY
Document Identification	
6.1.1 PPSP/QMS/ <name of document> QM for Quality manual, CD for control of document, CR for control of record, IA for internal audit, NCP for nonconforming product, CR for corrective action and PA for preventive action.	CDC/DCDC
6.1.2 Departmental core procedures (CP) involved in academic programme	
a. PPSP/< AcP>/<dept/unit>/CP<no>	CDC/DCDC/DC
b. PPSP/< AcP>/<dept/unit>/CP/<no> IR <serial no> for internal reference	Core Procedure: PPSP/PG/PAED/CP1
c. PPSP/< AcP>/<dept/unit>/CP/<no> ER <serial no> for external reference.	
d. PPSP/< AcP>/<dept/unit>/CP/<no> L/<serial no> for appendix.	
6.1.3 Departmental core procedures (CP) not involved in academic programme.	
a. PPSP/<dept/unit>/CP<no>.	CDC/DCDC/DC
b. PPSP/<dept/unit>/CP/<no> IR <serial no> for internal reference	Core Procedure: PPSP/Pent/CP1
c. PPSP/<dept/unit>/CP/<no> ER <serial no> for external reference.	
d. PPSP/< AcP>/<dept/unit>/CP/<no> L/<serial no> for appendix.	
Note: Documents already identified under other quality management systems can also be used where applicable.	

Internal Reference :
PPSP/PG/PAED/CP1/IR1

External Reference :
PPSP/PG/PAED/CP1/ER1

Appendix :
PPSP/PG/PAED/CP1/L1

5. ABBREVIATION

CDC : Chief Document Controller
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 PF : Phase coordinator
 PC : Programme Chairman
 IR : Internal Reference
 ER : External Reference
 R : Record
 L : Appendix

CP jabatan tidak ikut Control of Document dan Control of Record

Ketidakakuran kepada klausa mana?

7.5.2

Mewujudkan dan mengemaskini

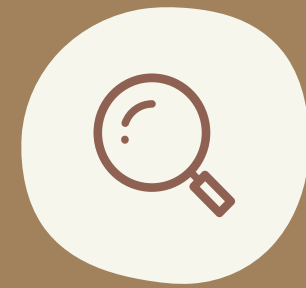
5.3

Peranan, tanggungjawab dan bidang kuasa organisasi

7.2

Kekompetenan

7.10 Quality Manual menyatakan Responsibility of **the Document Controller** to ensure that the most current documented information maintained is issued and followed



Aktiviti dalam CP tidak sama dengan amalan yang dilakukan di Jabatan

Ketidakakuran kepada klausa mana?

7.5.3.1

Maklumat didokumentasikan hendaklah dikawal bagi memastikan ia tersedia dan sesuai untuk digunakan

5.3

Peranan, tanggungjawab dan bidang kuasa organisasi

8.2.4

Perubahan keperluan untuk produk dan perkhidmatan

8.2.4 Perubahan keperluan untuk produk dan perkhidmatan

Organisasi hendaklah memastikan bahawa maklumat didokumentasikan yang relevan dipinda, dan bahawa orang yang berkaitan dimaklumkan tentang keperluan yang berubah, apabila keperluan untuk produk dan perkhidmatan diubah.

Just keep moving forward

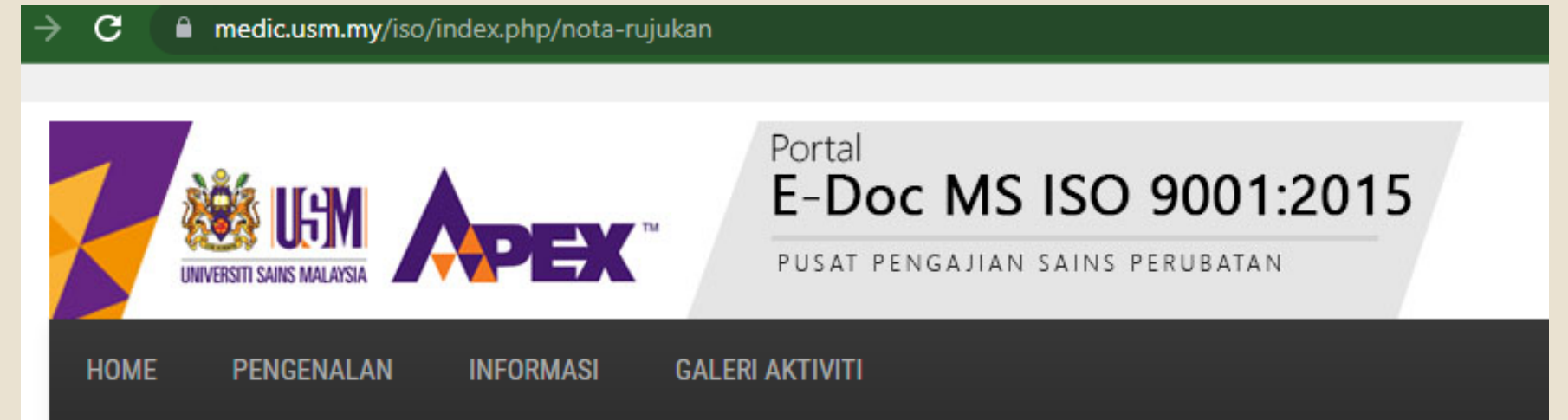
TERIMA KASIH



E-DOC PPSP



**Maklumat
didokumentasikan**



MUHAMAD FARIS IRFAN BIN CHE YUSOFF

Maklumat didokumentasikan

Adalah maklumat yang digunakan untuk menerangkan semua keperluan Sistem Pengurusan Kualiti

Plan				DO	Check	Act
4 Context of organization	5 Leadership	6 Planning	7 Support	8 Operation	9 Performance and Evaluation	10 Improvement
4.1 Understanding context	5.1 Leadership and commitment	6.1 Actions to address risks and opportunities	7.1 Resources	8.1 Operational planning and control	9.1 Monitoring, measurement, analysis and evaluation	10.1 General
4.2 Interested parties	5.2 Policy	6.2 Quality objectives and planning	7.1.2 People	8.2 Requirement for products & services	9.1.2 Customer satisfaction	10.2 Nonconformity and corrective action
4.3 Scope	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.1.3 Infrastructure	8.3 Design & Development	9.1.3 Analysis and evaluation	10.3 Continual improvement
4.4 QMS			7.1.4 Environment for the operation of processes	8.4 Control of externally provided process, product, services	9.2 Internal audit	
			7.1.5 Monitoring and measuring resources	8.5 Production and Service Provision	9.3 Management review	
			7.1.6 Organizational knowledge	8.6 Release of Products and Services		
			7.2 Competence	8.7 Control of nonconforming outputs		
			7.3 Awareness			
			7.4 Communication			
			7.5 Documented information			

