

USER MANUAL

FRONT END USER

Medical Device Centralised Online Application System (MeDC@St 2.0)

MODUL UTAMA - CAB

DISEDIAKAN OLEH :



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1.0 INTRODUCTION

This manual is prepared for the purpose of operational functions of Medical Device Centralised Online Application System.

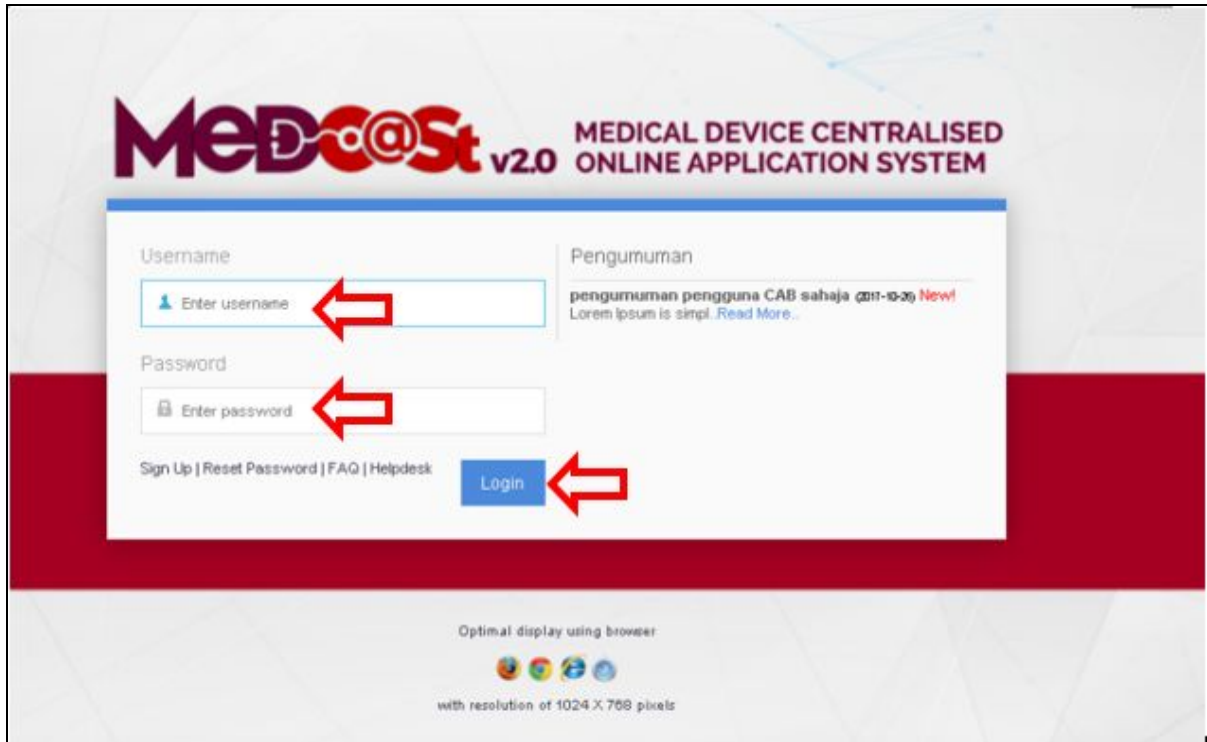
MeDC@St is a web-based Online Application System for Conformity Assessment Body Registration or CAB Registration. It is a centralized system where only one account needs to be created by an applicant to apply for Conformity Assessment Body Registration. This module that allows all CAB programme operations to run online and monitoring can be carried out in real time.

1.1 SYSTEM ACCESS

MeDC@st (Medical Device Centralised Online Application System) is developed using web-based method in which it utilizes the internet access via internet server. In order to access Medc@st, user has to key in the URL address onto the internet server as followed:

<https://medcast.mda.gov.my>

The screen below shows the expected webpage after the address has been key In.



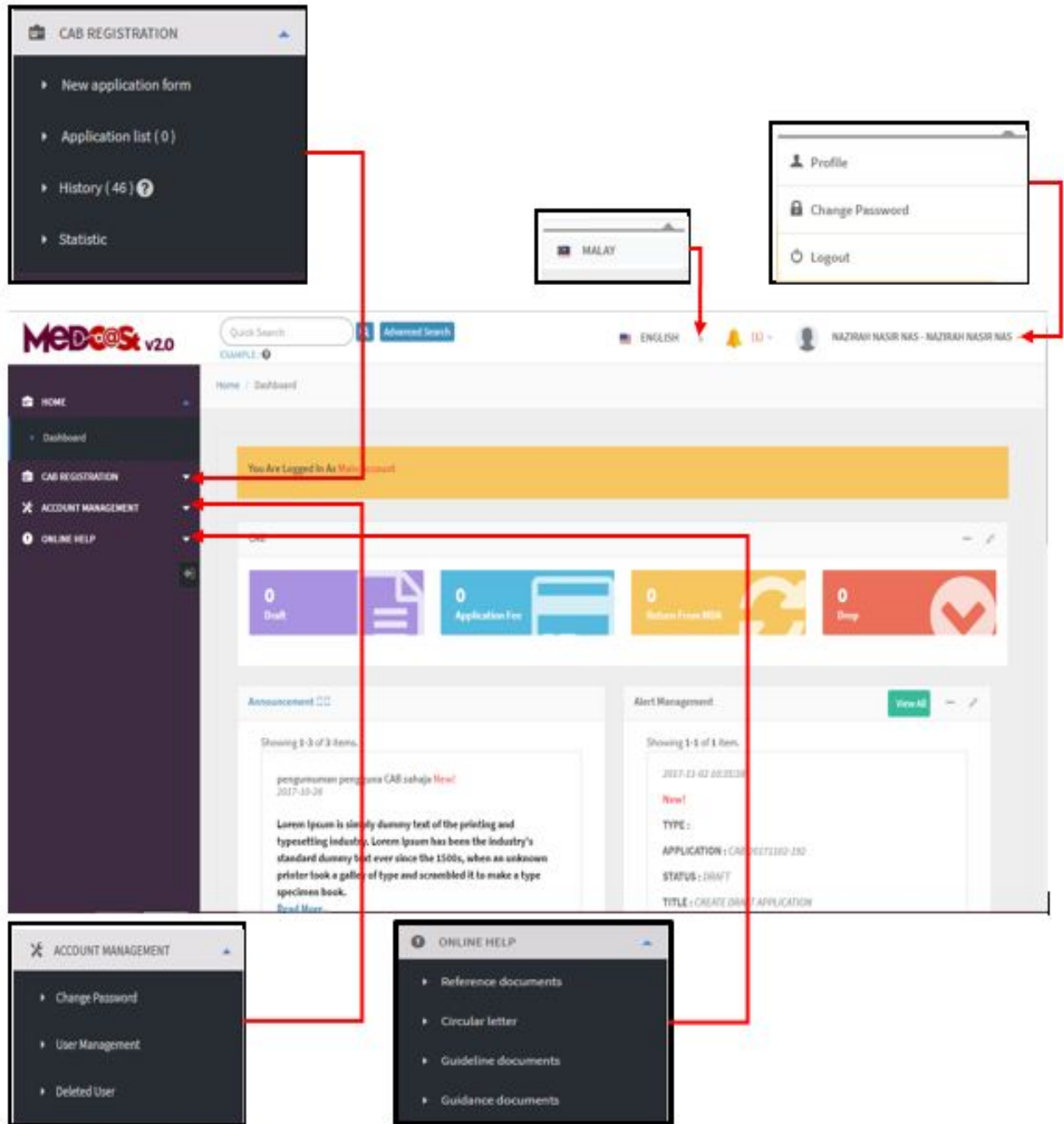
User has to log into the system using registered Username and its respective

Password. Click  to proceed.

2.0 FUNCTIONS

2.1 DASHBOARD

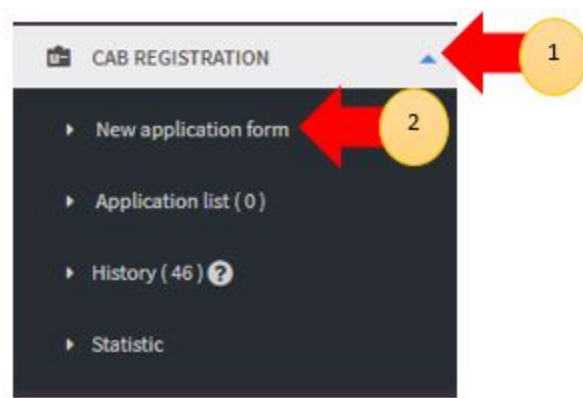
Below show the Dashboard page that will appear once CAB Module has logged into the system successfully.



2.2 MENU CAB REGISTRATION

Menu CAB Registration has four sub menu which are new application form, application list, history and statistics. User should click on menu CAB Registration at left side menu for drop list sub menu CAB module.

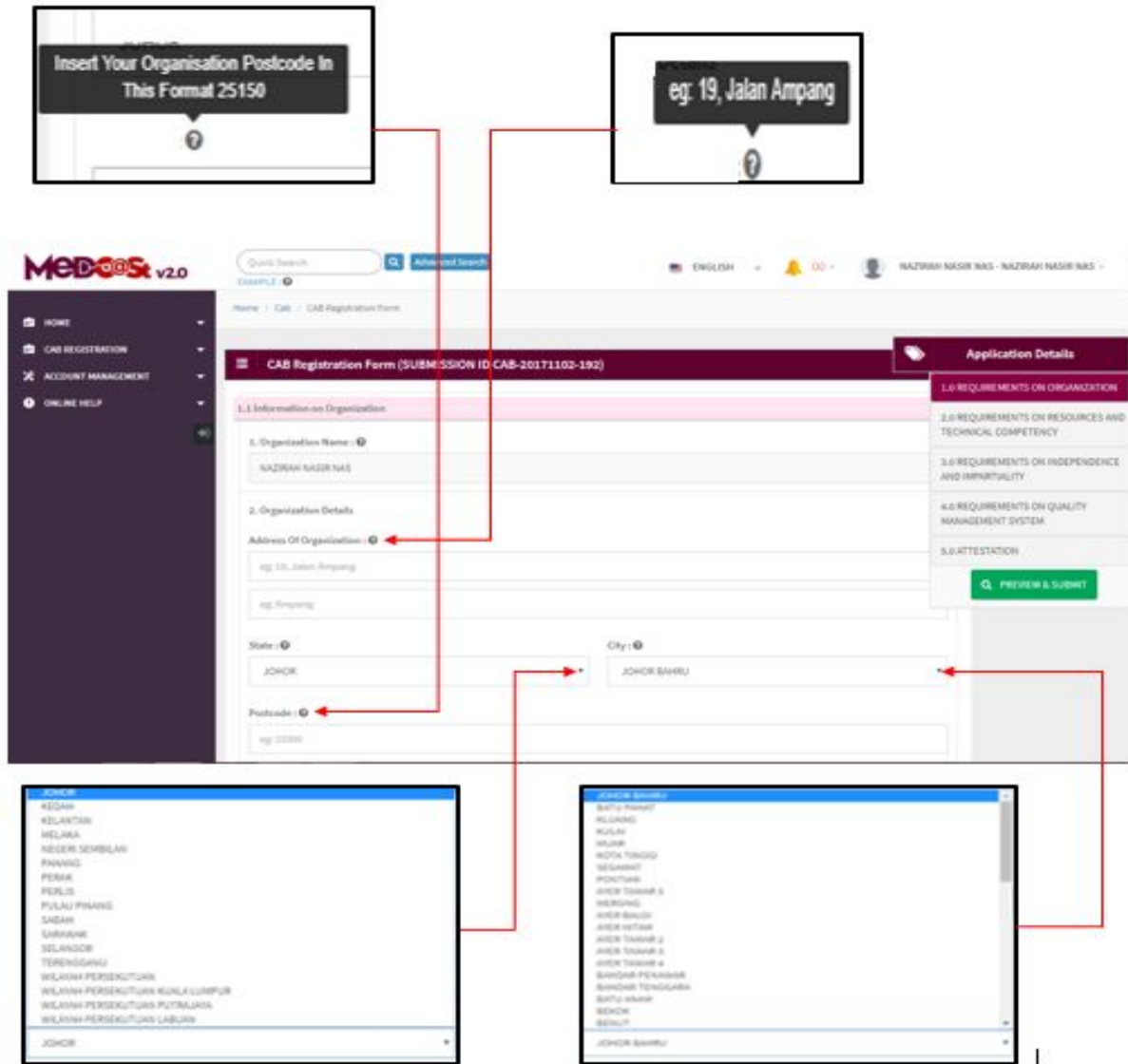
2.2.1 NEW APPLICATION FORM



First, user should click at sub menu **CAB REGISTRATION** to list down the sub menu **New application form**. After that, user can click at sub menu **New application form** to apply the registration form for CAB Registration.

The application form will appear. The figure below shows the application form for applicant fill it. The user should fill all CAB form. There has five sections which are:

- 1.0 Requirement on organization
- 2.0 Requirement on Resources and Technical Competency
- 3.0 Requirement on Independence and impartiality
- 4.0 Requirement on quality management system
- 5.0 Attestation



Section 1.0 Requirements on organization


1.1 Information on organization

1. Organization name

The name appear that already have been made when user sign up in account. System already fill this textbox. User cannot edit that data in textbox.

2. Organization details

- Address of organization

User should click at  to see the format and follow example format address that shown in figure above(eg.19,Jalan Ampang). User fill in address in the form textbox.


- State

User should click at drop down list to select the state that has shown in figure above.


- City

If user select the state, automatically the city will appear in form and user should select specific city.


- Postcode

The user should click at  to see the format and fill the form based on the format given. The field must contain exactly five numeric. If user fill the form with the alphabet or more than five number, the message will appear “Field must contain exactly 5 numeric.”

3. Telephone No.


The user must fill in the number only and click at  to see the format. User should follow the format shown in the figure below. If user fills in the form except number, the message “Organization Telephone No must be an integer.”

4. Fax No.

The user must fill in the number only and click at  to see the format. User should follow the format that shown in figure.If user fill in the form except number, the message “Organization Fax No must be an integer.”


5. Email Address(general)

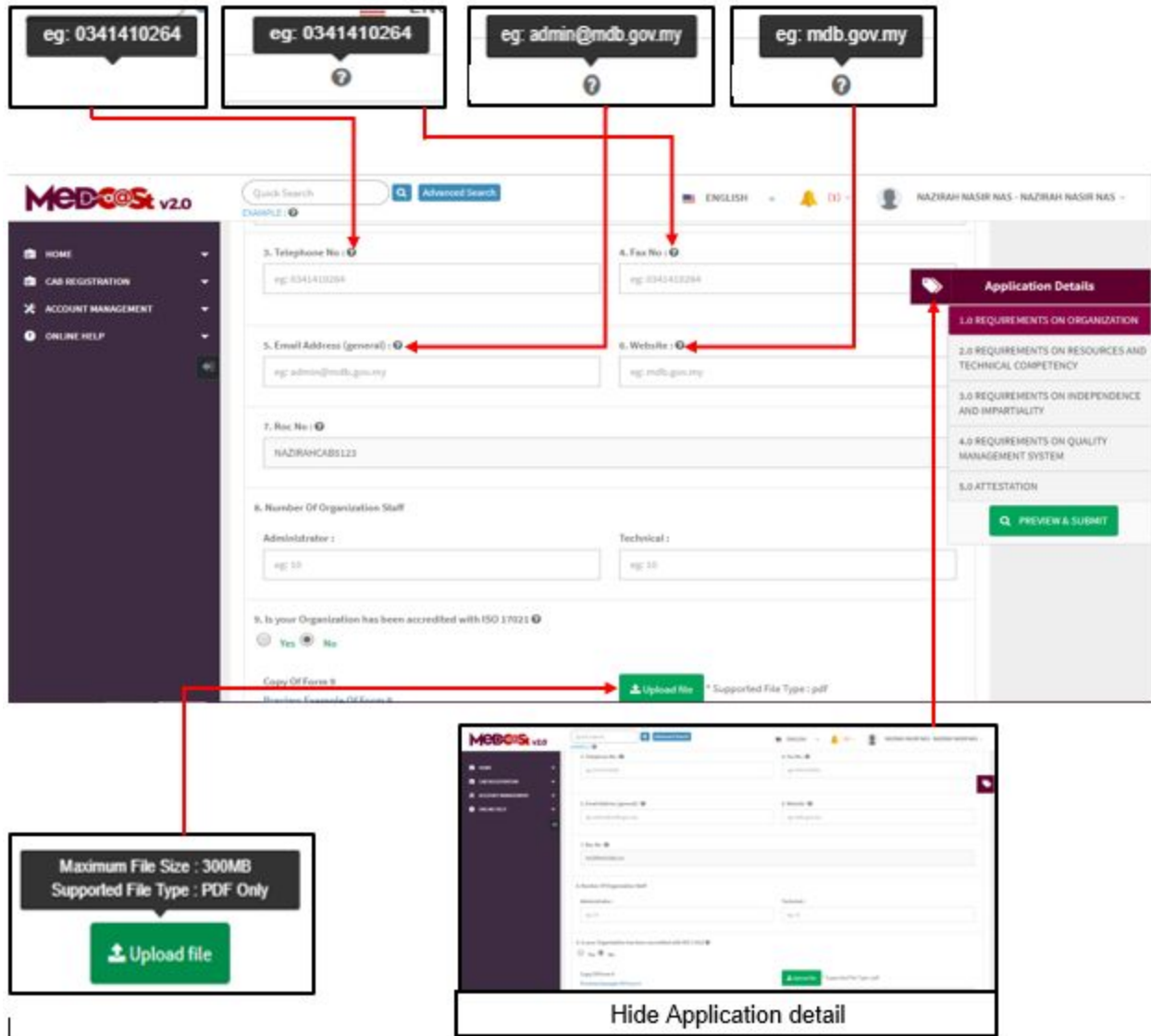
User must fill the email based the format that shown in figure. User should

click at  to see the format. The symbol "@" must have in email. If user fill the form incorrectly or not follow the format, the message will appear is "

Organization Email is not a valid email address.

6. Website

User must fill the website based format that given. User should click at  to see the format. If user fill the form incorrectly or not follow the format, the message will appear is "Website Address not valid, web address must start with www and ends with TLD such as .org .com .net : EXAMPLE : www.medicalinfo.com".



7. Roc No

The Roc No will appear already in the form where are user has been made in sign up. The form cannot be edited. The Roc No is Registration No.

8. Number of organization staff

The user must filled with number only.

- Administrator

If user fill the form with alphabet or incorrectly, the message will appear is
 “Organization Administrator Number must be an integer.”.


- Technical

If user fill the form with alphabet or incorrectly, the message will appear is
 “Organization Technical Number must be an integer.”.

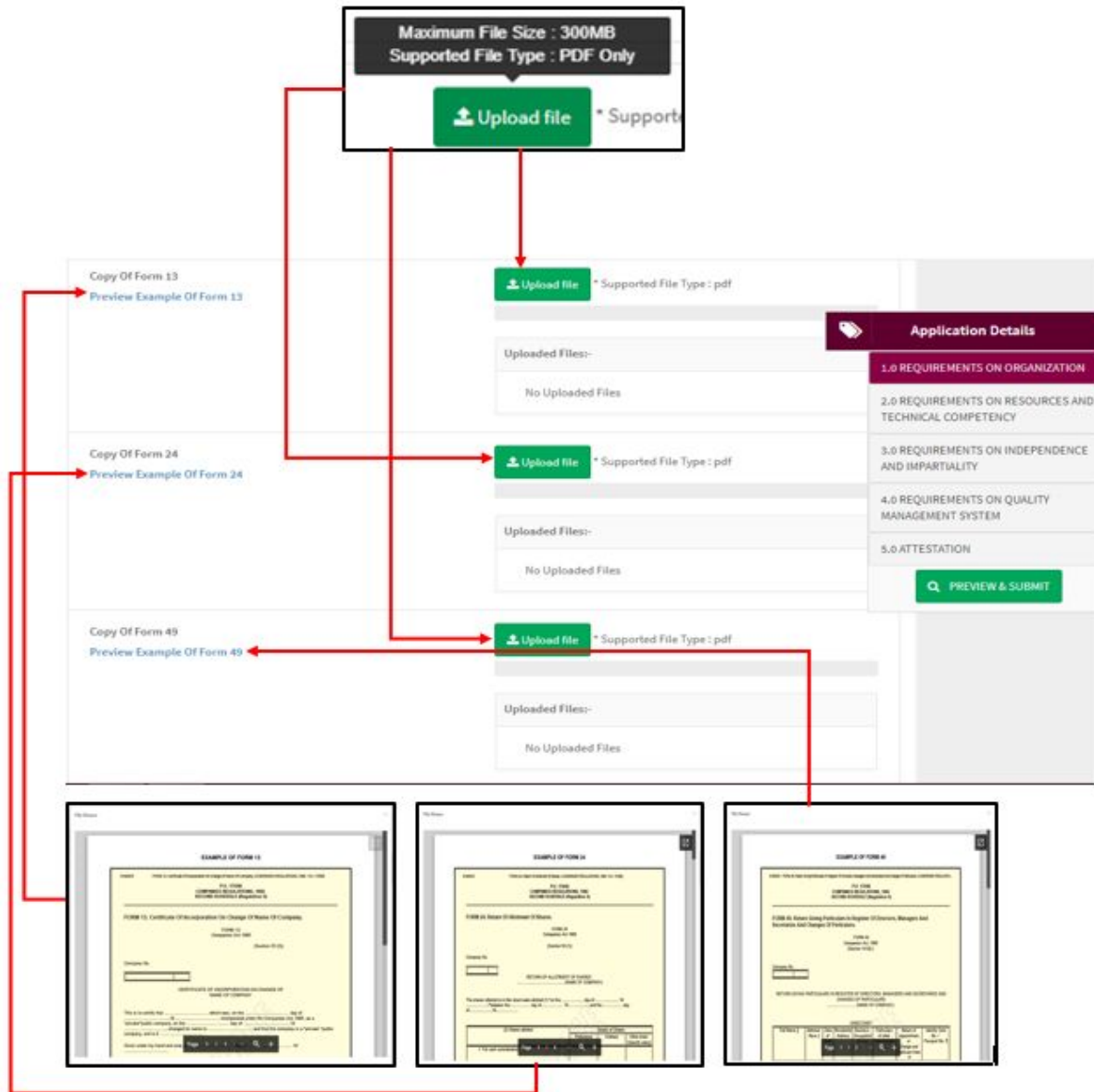
9. Is your organization has been accredited with ISO 17021. Yes No
- The user should click radio button whether “Yes” or “No”. If user clicks the radio button “No”, Form that user should upload will appear.

- Copy of Form 9




User must click at button  untuk upload file PDF only and not more than 300MB for file size. If user upload file not in format PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.



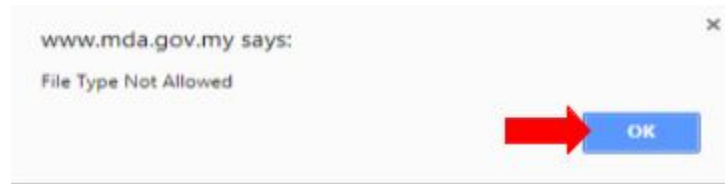


- Copy of Form 13

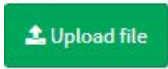
User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ **Preview Example of Form 13**” and example form will be appear. Beside that, user can download and print


by clicking symbol  .If user upload file except PDF, the message

will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.




- Copy of Form 24


User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example of Form 24](#)” and example form will appear. Beside that, user can download and print by

clicking symbol . If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.

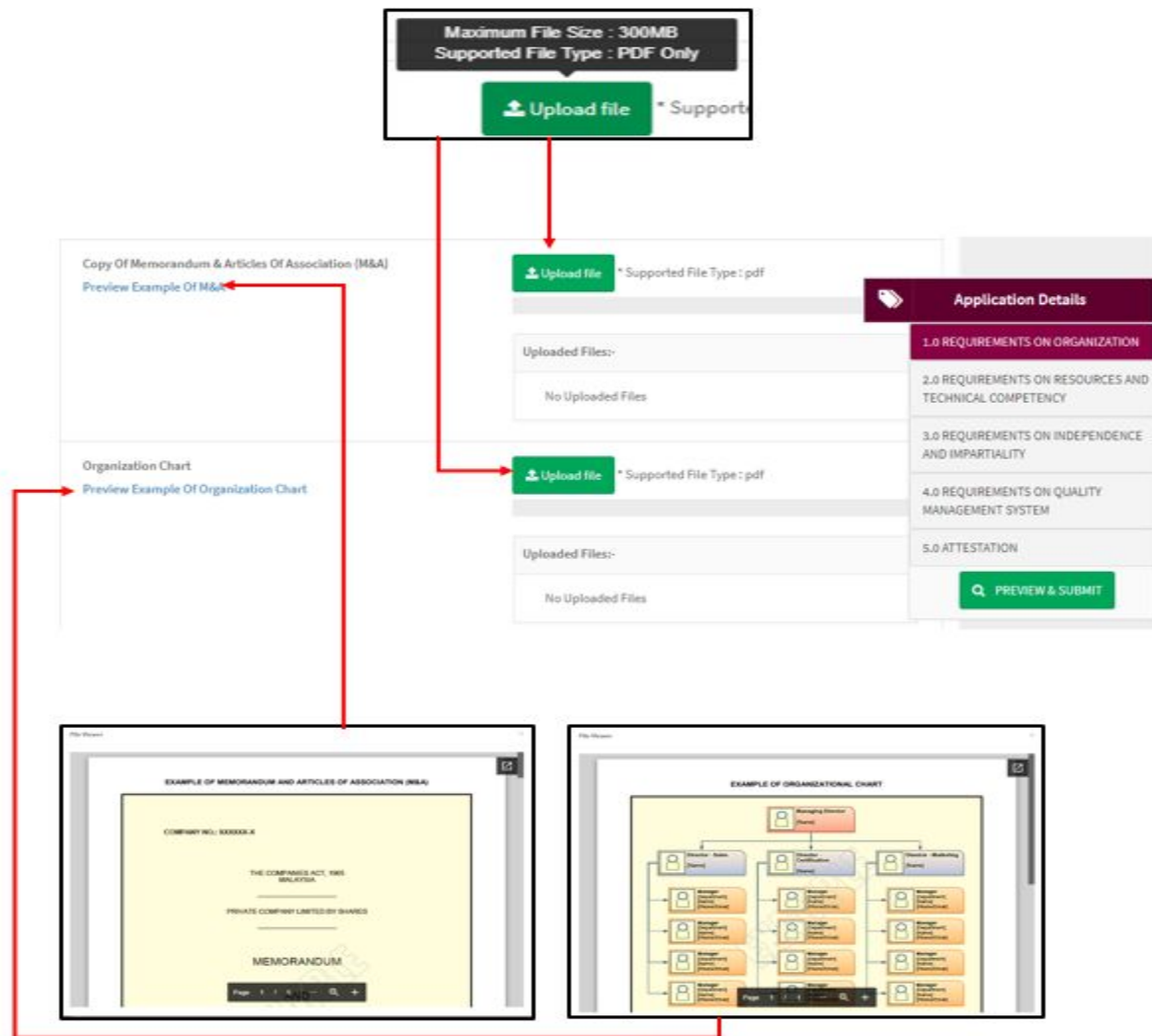


- Copy of Form 49

User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example of Form 49](#)” and example form will appear. Beside that, user can download and print by


clicking symbol . If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click


“ok” to proceed in the system.



- Copy of Memorandum & Articles of Association (M&A)




User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example Of M&A](#)” and example form will


appear. Beside that, user can download and print by clicking symbol  . If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.



- Organization Chart



User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example Of Organization Chart](#)” and example form will appear. Beside that, user can download and print by

clicking symbol  . If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to



proceed in the system.


- Is your organization has been accredited with ISO 17021.



The user should click radio button whether Yes or No. If user click radio button “Yes”, Form that user should upload will appear. The figure below show the form that make decision YES.

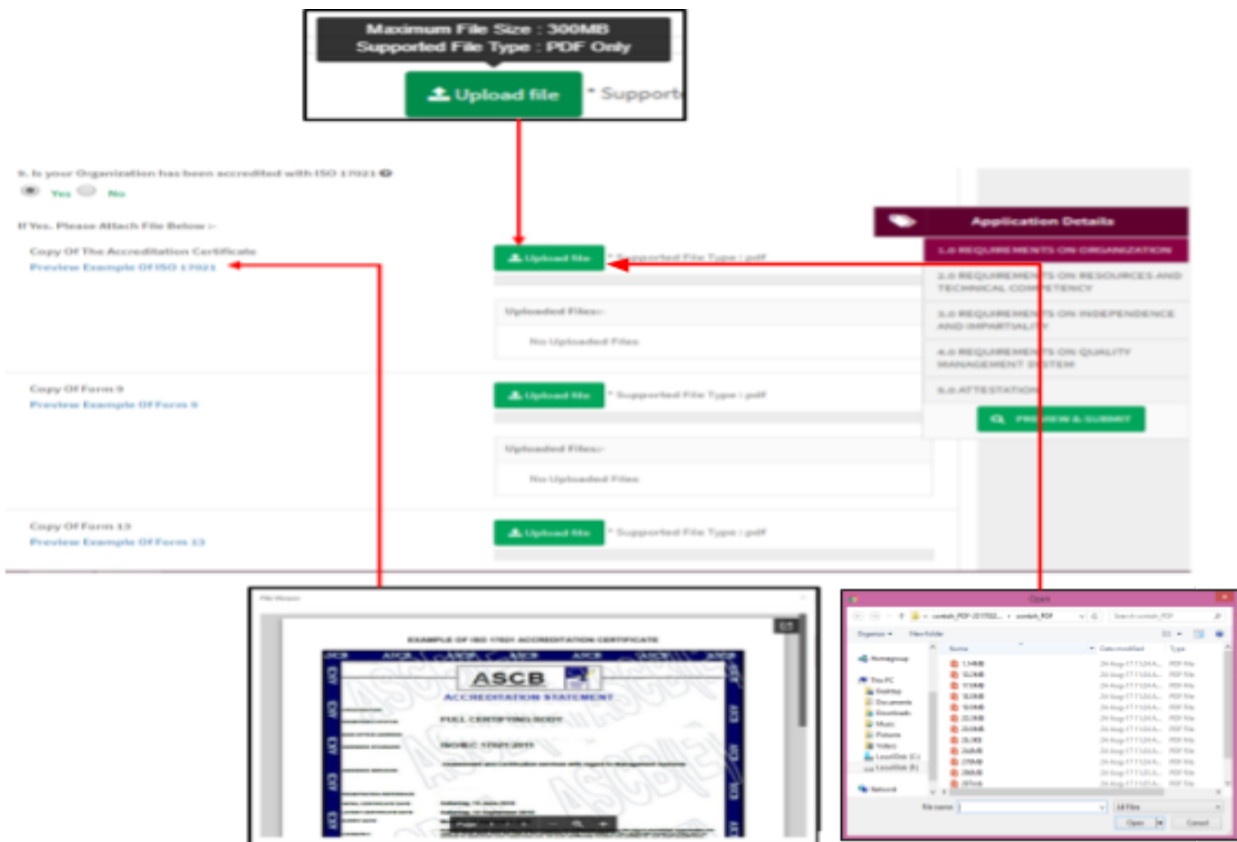
- Copy of the Accreditation Certificate



User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example Of ISO 17021](#)” and example form will appear. Beside that, user can download and print by clicking symbol



. If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.



After that, user should fill the form of Section 1.2 which is Information on Person Responsible(Malaysian). All form that will be shown in the figure below.

The screenshot displays the '1.2 Information On Person Responsible (Malaysian)' section of the application form. The form is divided into several numbered fields:

- 1. Person Responsible Salutation :** A dropdown menu with options: DATUK, DATO, DATIN, PROF, DR, IR, MR, MRS, PUWA, WS, EN.
- 2. Person Responsible Name :** A text input field with the example 'eg: Ahmad Saufiyuddin'.
- 3. Nric No / Passport :** A text input field with the example 'eg: 670413345107'. A callout box above it states: 'Insert Your NRIC/Passport In This Format 961223120000/A000000000'.
- 4. Designation :** A dropdown menu with 'OTHER' selected. A callout box below it shows a list of designations: Director, Managing Director, Manager, General Manager, MD Director, CEO, President, Vice President, and OTHER.
- 5. Handphone No :** A text input field with the example 'eg: 0341410264'. A callout box below it shows the example 'eg: 0341410264'.
- 6. Office No :** A text input field.

On the right side of the form, there is a sidebar titled 'Application Details' with a list of requirements: 1.0 REQUIREMENTS ON ORGANIZATION, 2.0 REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY, 3.0 REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY, 4.0 REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM, and 5.0 ATTESTATION. A green 'PREVIEW & SUBMIT' button is located at the bottom of the sidebar.

1.2 Information On Person Responsible(Malaysian)

1. Person Responsible Salutation

User should select type of salutation which is click on form and the dropdown list textbox the salutation will be appear like figure above shown.

2. Person Responsible Name

The user fill in responsible name in the form. Example will be appear at the

form. 

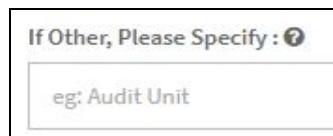
3. Nric No/Passport

The user must fill in the form according to the format displayed on the figure above.

4. Designation

The user should select the type of designation at drop down list textbox that shown in figure above.

- If user choose OTHER, form "If Other, Please Specify"



will be displayed and the user must fill it.


5. Handphone No.

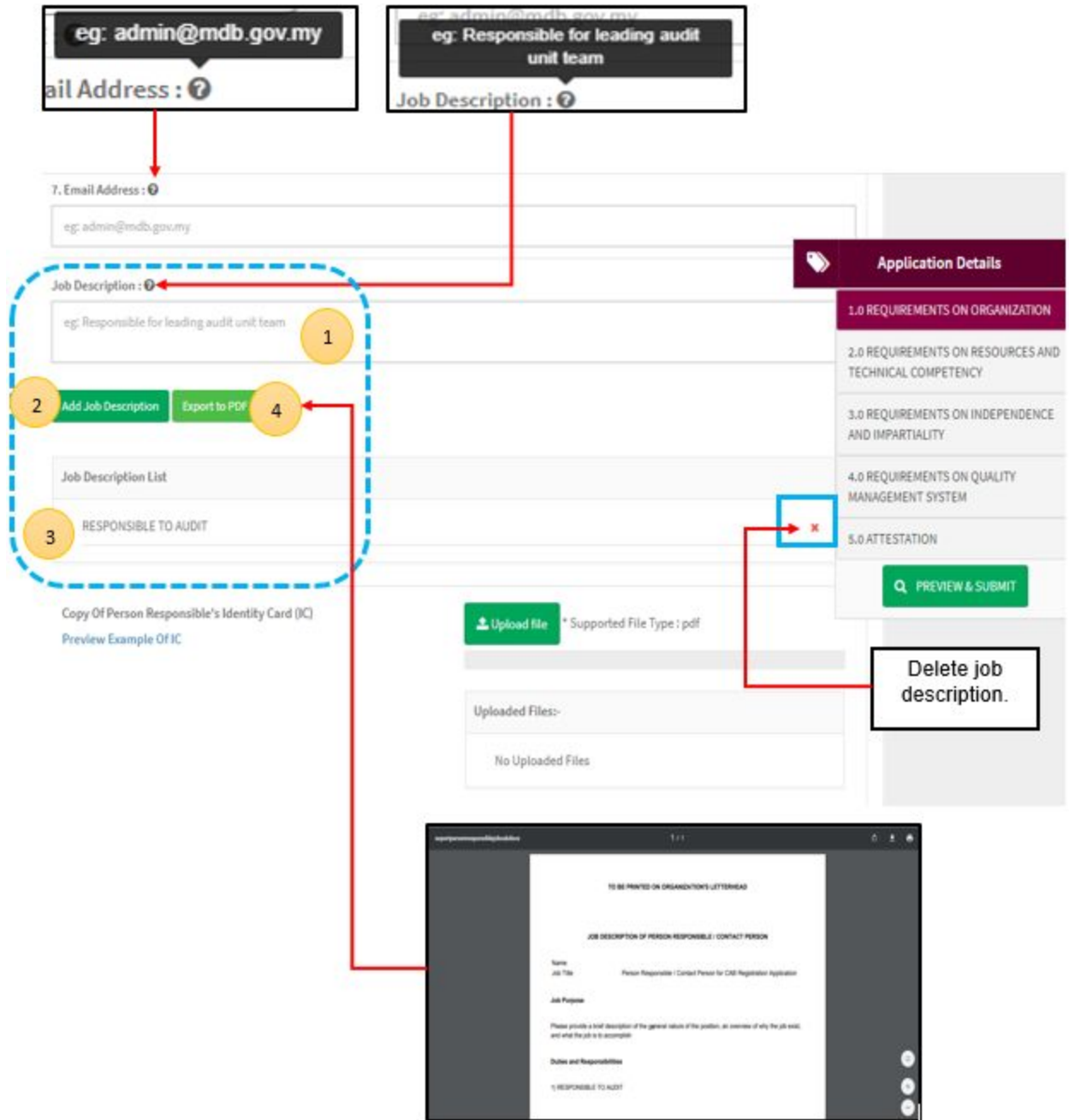
The user must fill the Handphone No in an integer and user can see the

format with click at  . The format will appear like shown in figure above. If

user fills in the form except number or incorrectly, the message "Person Responsible Handphone No must be an integer." will appear.


6. Office No.

The user must fill the Person Responsible Office No in an integer. User can see the format which click at  and display formats like Handphone No. If user fill in the form except number or incorrectly, the message "Person Responsible Office No must be an integer." will be appear.



7. Email Address

User must fill the email based the format that shown in figure above. User

should click at  to see the format. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will appear is “

Person Responsible Email is not a valid email address.”.

8. Job Description

1

- User must fill in the description in the form.

2

- User should click at button



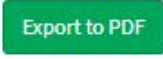
3

- The job description will be display at form job description list.

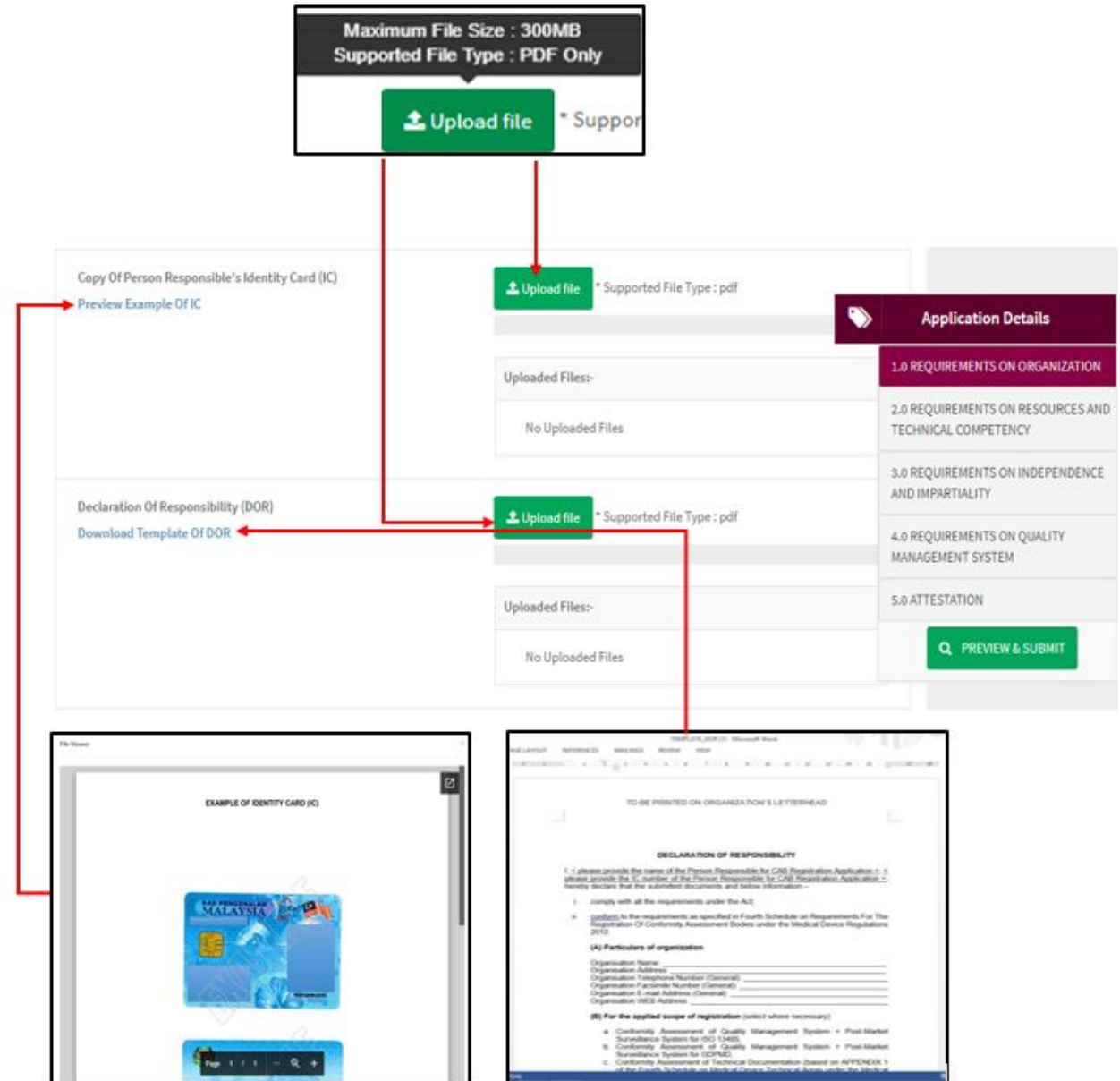
Job Description List
RESPONSIBLE TO AUDIT

4


- User should click




to view in PDF and user can download and print the file.



- Copy of Person Responsible Identity Card(IC)

User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ **Preview Example Of IC**” and example form will appear.


Beside that, user can download and print by clicking symbol . If user upload file except PDF, the message will appear at the system which is “File

Type Not Allowed". User should click "ok" to proceed in the system.



- Declaration Of Responsibility(DOR)



User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can download the example form which are user click the link "[Download Template Of DOR](#)" and automatically file will be downloaded. If user upload file except PDF, the message will appear at the system which is "File Type Not Allowed". User should click "ok"



to proceed in the system.

1.3 Information On Contact Person(Malaysian)

- Same as person Responsible:

The user should click the radio button "Yes" or "No". If user choose "Yes",



, the form not display in this application.

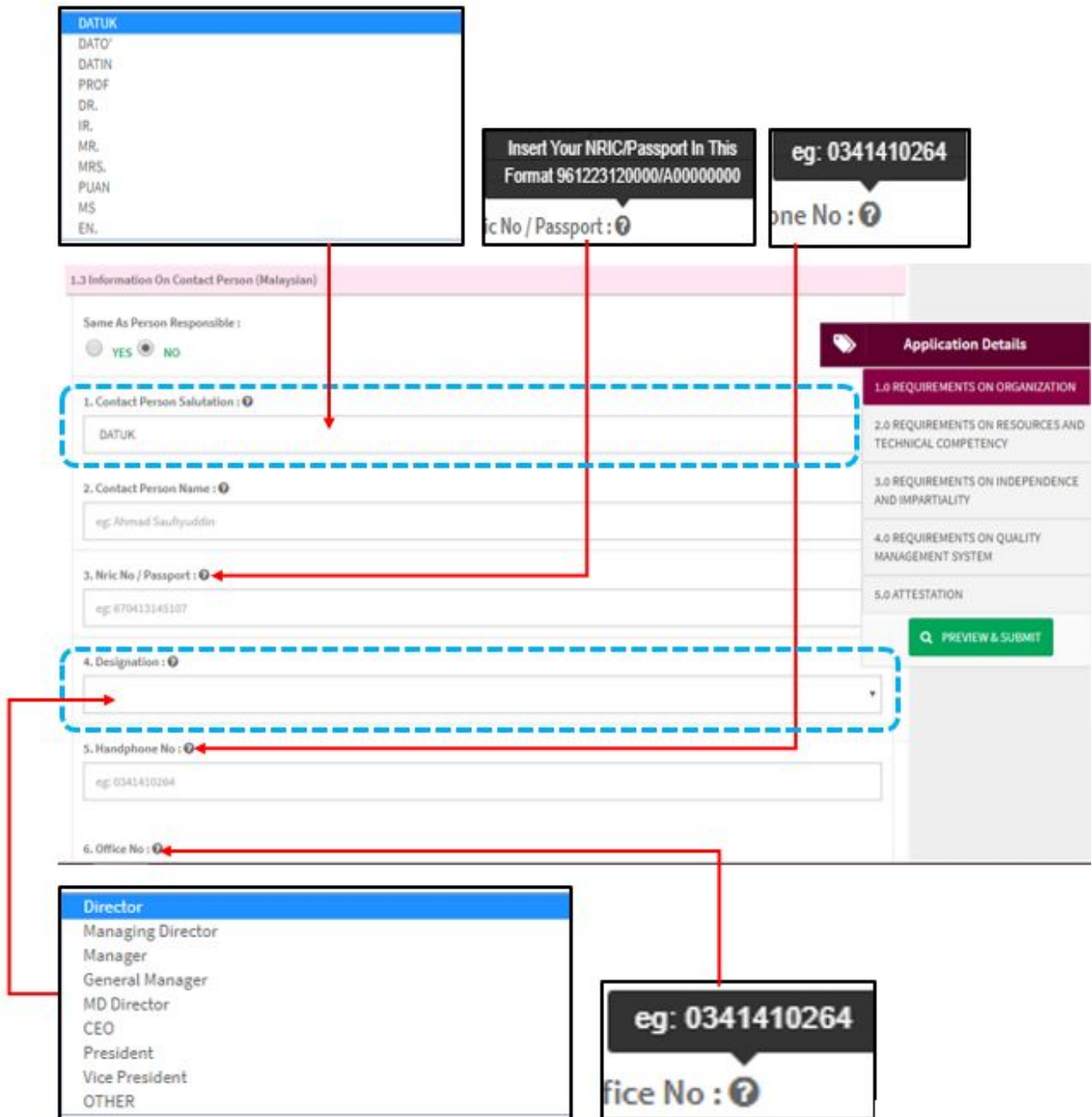


If user choose "No", the form for application will be appeared.



1. Contact Person Salutation

User should select type of salutation which is click on form and the dropdown list textbox the salutation will be appear like figure below shown.



2. Contact Person Name

The user fill in the contact person's name in the form. Example will be appear



at the form .

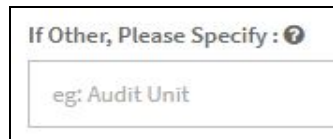
3. Nric No/Passport

The user must fill in the form according to the format displayed on the figure above.

4. Designation


The user should click at the form and select the type of designation at dropdown list textbox that shown in figure above.

- If user choose OTHER, form "If Other, Please Specify"




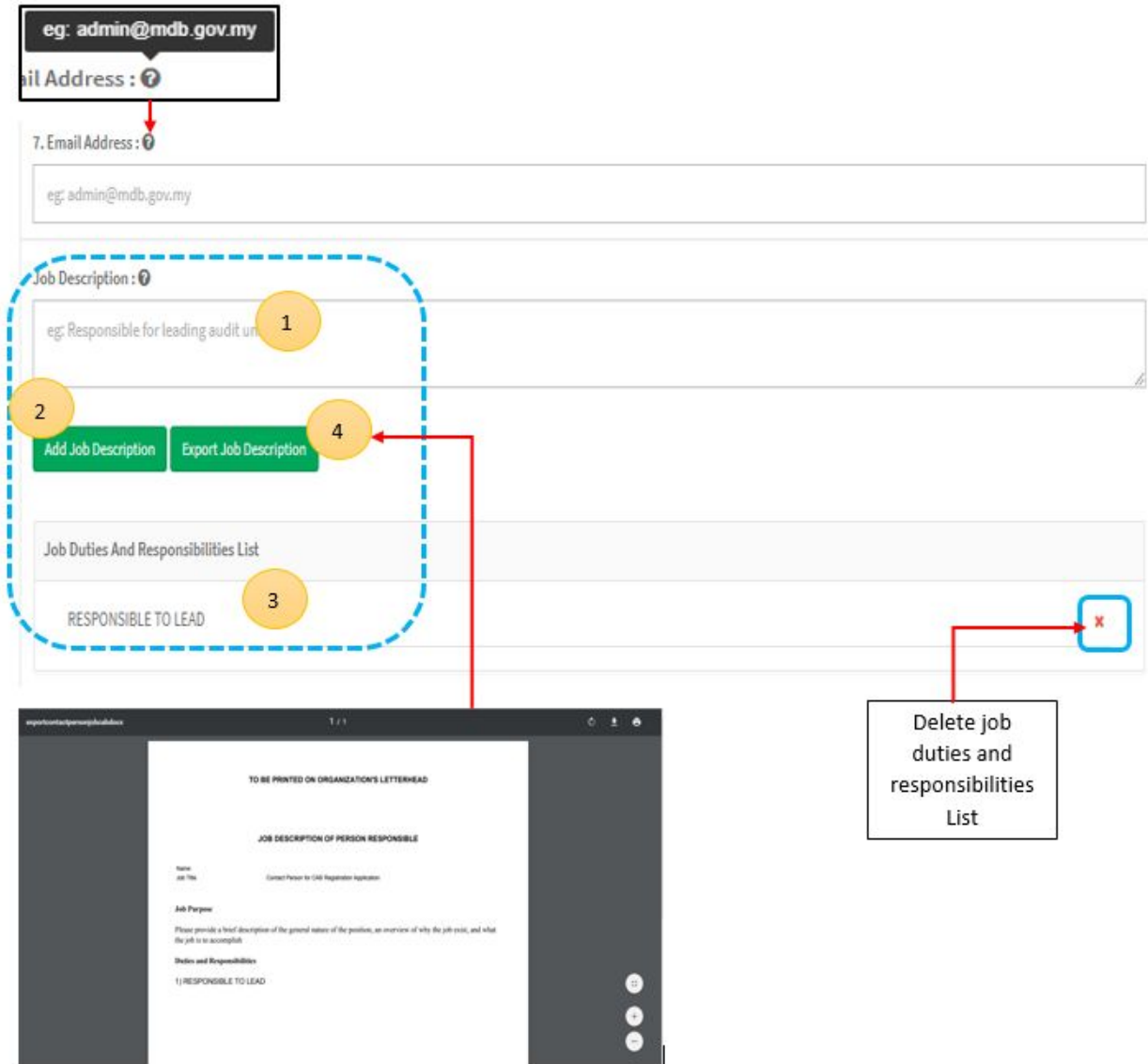
will be displayed and the user must fill it.

5. Handphone No.


The user must fill the Handphone No in an integer and user can see the format with click at  . The format will appear like shown in figure above. If user fills in the form except number or incorrectly, the message "Contact Person Hp No must be an integer." will appear.

6. Office No.

The user must fill the Office No in an integer. User can see the format which click at  and display formats like Handphone No. If user fill in the form except number or incorrectly, the message "Contact Person Office No must be an integer." will appear.



7. Email Address

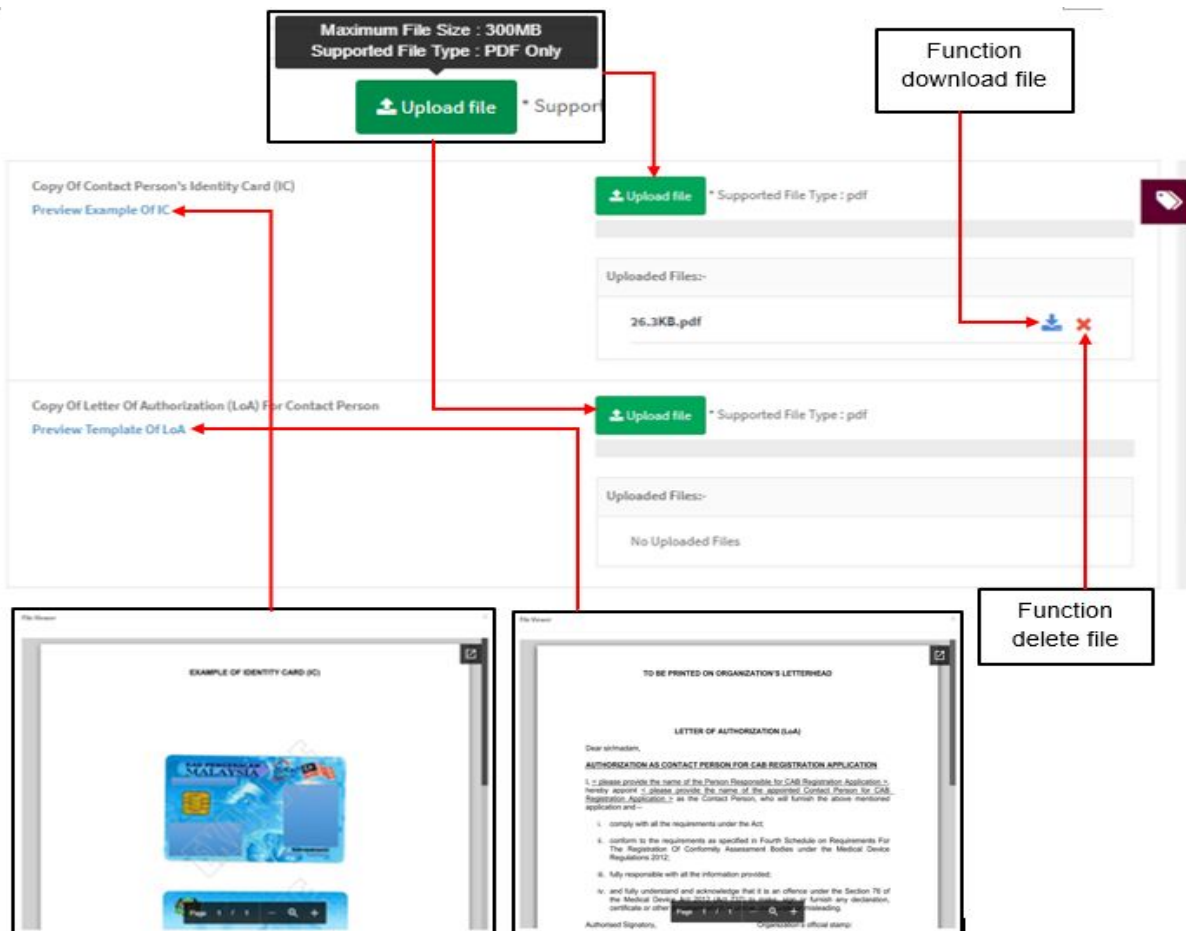
User must fill the email based the format that shown in figure above. User should click at  to see the format. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will appear is “**Contact Person Email Address is not a valid email address.**”.

8. Job Description


- 1 - User must fill in the description in the form.
- 2 - User should click at button **Add Job Description**.
- 3 - The job description will be display at form job description list.


Job Duties And Responsibilities List
RESPONSIBLE TO LEAD

- 4 - User should click **Export to PDF** to view in PDF and user can download and print the file.



- Copy of Contact Person's Identity Card(IC)


User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link "[Preview Example Of IC](#)" and example form will appear.

Beside that, user can download and print by clicking symbol . If user upload file except PDF, the message will appear at the system which is "File Type Not Allowed". User should click "ok" to proceed in the system.



- Copy of Letter of Authorization (LoA) For Contact Person.

User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link "[Preview Template of LoA](#)" and example form will

appear. Beside that, user can download and print by clicking symbol . If user upload file except PDF, the message will appear at the system which is "File Type Not Allowed". User should click "ok" to proceed in the system.



1.4 Information on Larger Organization Structure

1. Is Your Organization Having Any Relationship / Link With Any Larger Organization Outside Malaysia?

The user should click the radio button "Yes" or "No". If user choose "No"

YES NO

, the form not display in this application.



1.4 Information on Larger Organization Structure

1. Is Your Organization Having Any Relationship / Link With Any Larger Organization Outside Malaysia? ?

YES NO

If user choose "Yes" YES NO , the form will be appear in this application.

Legend:
 SUBSIDIARY
 AUTHORIZED AGENT
 PARTNERSHIP AGREEMENT
 OTHER

1.4 Information on Larger Organization Structure

1. Is Your Organization Having Any Relationship / Link With Any Larger Organization Outside Malaysia? YES NO

If Yes, Please Select Your Organization's Relationship / Link With That Larger Organization :

OTHER

If Other, Please Specify :

NO RELATIONSHIP

2. Larger Organization Name :

3. Address Of Organization :

Copy Of Agreement With The Larger Organization
 Preview Example Of Agreement

Upload file * Supported File Type : pdf

Application Details

- 1.0 REQUIREMENTS ON ORGANIZATION
- 2.0 REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY
- 3.0 REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY
- 4.0 REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM
- 5.0 ATTESTATION


PREVIEW & SUBMIT

- If Yes, Please Select Your Organization's Relationship/Link With That Larger Organization
 The user must click at the form textbox and dropdown list will appear.
 The user must select one of them. If user select "OTHER", user should fill the form "If Other, Please Specify:"


2. Larger Organization Name

The user must fill the name of organization and click to see the format.
 The user should follow the format that shown in figure above.

3. Address of Organization

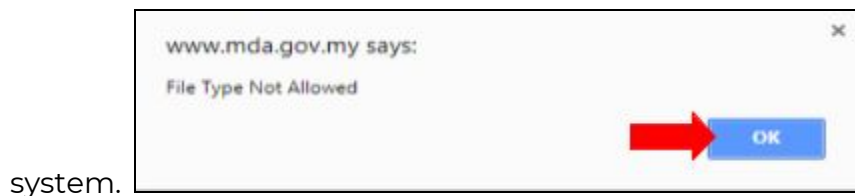
User should click at  to see the format and follow example format address that shown in figure above(eg.19,Jalan Ampang). User fill in address in the form textbox.

- Copy of Agreement with The Larger Organization


User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example of Agreement](#)” and example form will appear. Beside that, user can download and print by clicking symbol




. If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the

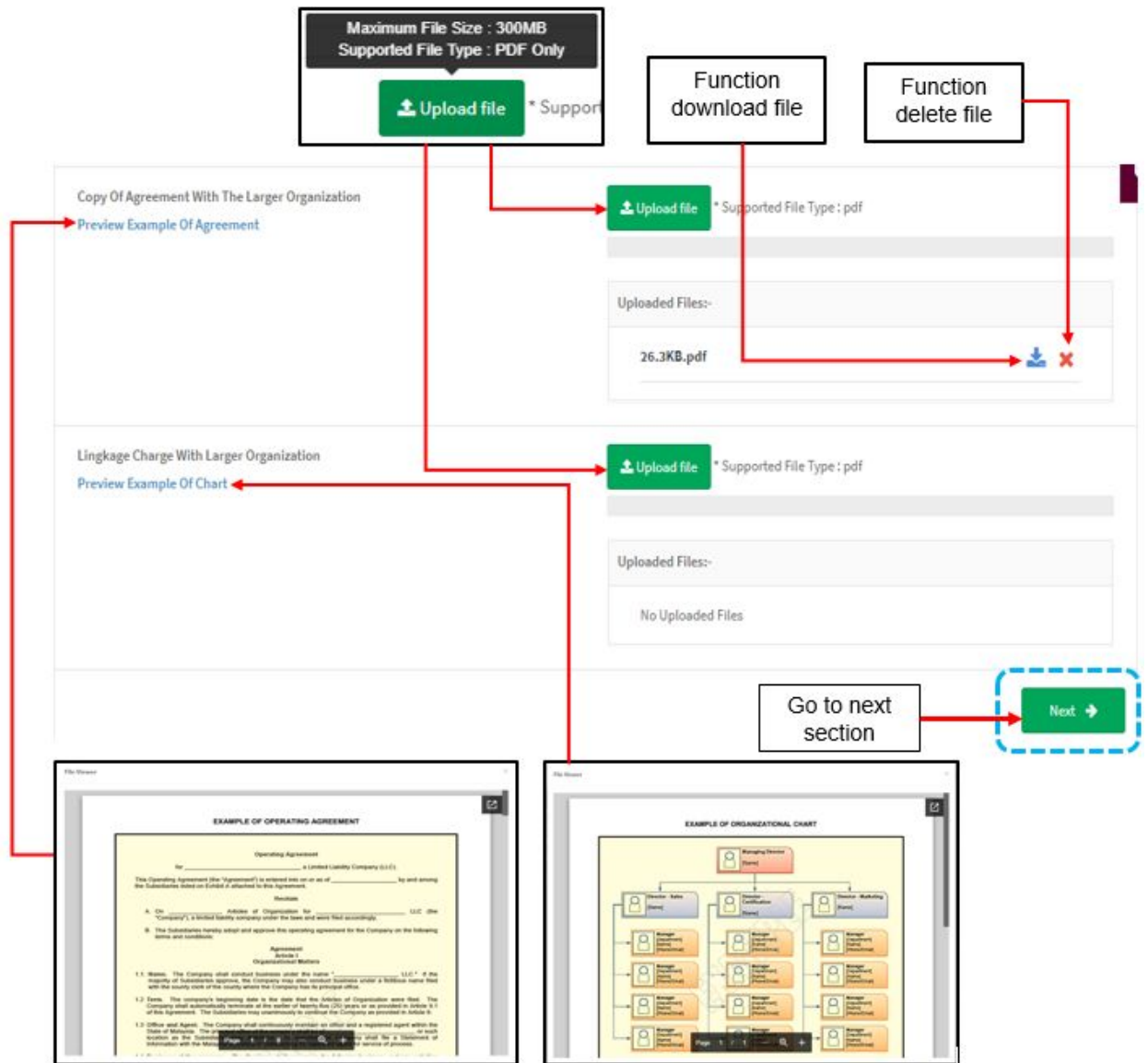


- Linkage Charge with Larger Organization

User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “ [Preview Example of Chart](#)” and example form will

appear. Beside that, user can download and print by clicking symbol  . If user upload file except PDF, the message will appear at the system which is “File Type Not Allowed”. User should click “ok” to proceed in the system.





Section 2.0 Requirements on Resources and Technical Competency

2.1 Information on the Scope(s) to be Applied

There have three scope to be applied which are:



- ISO 13485 + POST-MARKET SURVEILLANCE SYSTEM
- GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD) + POST-MARKET SURVEILLANCE SYSTEM
- MEDICAL DEVICE TECHNICAL AREAS

The user should click button check box that user want to be applied first before click

REGISTRATION OF PERSONNEL

1 User click button checkbox

2 Click button personnel

2.1 Information on the Scope(s) to be Applied

- ISO 13485 + POST-MARKET SURVEILLANCE SYSTEM
- GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD) + POST-MARKET SURVEILLANCE SYSTEM
- MEDICAL DEVICE TECHNICAL AREAS

To APPLY and/or ADD personnel registration, please click **REGISTRATION OF PERSONNEL**

No	Submission ID	Application Type Name	Application Status	Created By	Personnel Name	Personnel Nric
No results found.						

3

Personnel Registration Form:

- 1. Submission: [Dropdown]
- 2. Name: [Text]
- 3. Nationality: [Dropdown]
- 4. Work / Research: [Text]

Please upload the Copy of Identity Card (IC) / Passport / Work Permit. **Upload** [Button] [Button]

The user must click button “Registration of Personnel” for fill the form of CAB Personnel Application. The figure above also shown the form for scope personnel in

3

The user must fill the form of CAB Personnel Application. The figure below shows the CAB Personnel Application form to user filled it.

The screenshot displays the 'CAB Personnel Application' form. The 'Personnel Details' section includes the following fields:

- 1. Salutation: A dropdown menu with 'DATUK' selected. A callout box lists other options: DATO', DATIN, PROF, DR., IR., MR., MRS., PUAN, MS, EN.
- 2. Name: A text input field.
- 3. Nationality: A dropdown menu with 'MALAYSIAN' selected. A callout box lists 'MALAYSIAN' and 'NON-MALAYSIAN'.
- 4. Nric / Passport: A text input field. A callout box provides the format: 'Insert Your NRIC/Passport In This Format 961223120000/A000000000' and shows an example of an NRIC card.

Below the form, there is an 'Upload file' button with the text '* Supported File Type : pdf'. A callout box specifies: 'Maximum File Size : 300MB Supported File Type : PDF Only'. A preview area shows 'Uploaded Files:-' with 'No results found.' and a link to 'Preview: Example of IC'.

Annotations include a 'User click to scroll down' box pointing to the scrollbar on the right, and red arrows connecting the callout boxes to their respective form fields.

2.2 Personnel Details

1. Salutation

The user should click at form textbox and the dropdown list will appear. User must select one of them based user's salutation.


2. Name

The user should fill the name in field that provided.

3. Nationality


The user clicks at the form textbox to display the dropdown list. User must select whether "MALAYSIAN" or "NON-MALAYSIAN".


4. Nric/Passport

User should click at  to see the format IC that shown in figure above. The user must fill the form with number only. If user fill the form with alphabet or incorrectly, the message "Field must contain exactly 12 numeric." will appear.

- Please upload the Copy of Identity Card(IC)/Passport/Work Permit

The symbol "*" means required field. The user must required to upload the file.

A green rectangular button with a white upload icon and the text "Upload file".

User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link "[Preview Example Of IC](#)" and example form will appear.


Beside that, user can download and print by clicking symbol .

5. Employment status

The user must click at the form textbox and dropdown list will appear. The user should select whether "SUBCONTRACTOR" or "PERMANENT" that show in the figure below.

- Please upload the Copy of Employment Letter or Subcontractor Agreement.

The symbol “*” means required field. The user must compulsory to upload the

file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which are user click the link “[Preview:Example of Agreement](#)” and example form will appear. Beside that, user can download and print by clicking symbol



. User also can preview the file that upload with click at the file name

Uploaded Files:-



26.3KB.pdf 

. The user also click at  to download the file and click  to delete the file.

6. Handphone No.

The user must fill the Personnel Hp No in an integer and user can see the format



eg: 0341410264

with click at  . The format will appear  . If user fills in the form except number or incorrectly, the message “Personnel Hp No must be an integer.” will appear.

7. Office No.

The user must fill the Personnel Office No in an integer. User can see the format


eg: 0341410264

which click at  . The format will appear  .If user fill in the form except number or incorrectly, the message “Personnel Office No must be an integer.” will appear.

8. Email

User must fill the email based the format. User should click at  to see the

eg: admin@mdb.gov.my


format. The format will appear . The symbol “@” must has in email. If user fill the form incorrectly or not follow the format, the message will appear is “ Personnel Email is not a valid email address.”.

PERMANENT
SUBCONTRACTOR

Maximum File Size : 300MB
Supported File Type : PDF Only

Upload file


CAB Personnel Application


5. Employment Status : 
SUBCONTRACTOR


* Please upload the Copy of Employment Letter or Subcontractor Agreement :
Preview: Example of Agreement

Upload file

Uploaded Files:-
26.3KB.pdf

6. Handphone No : 
eg: 0341410264

7. Office No : 
eg: 0341410264

8. Email : 


Function download file

Function delete file


Academic Qualification

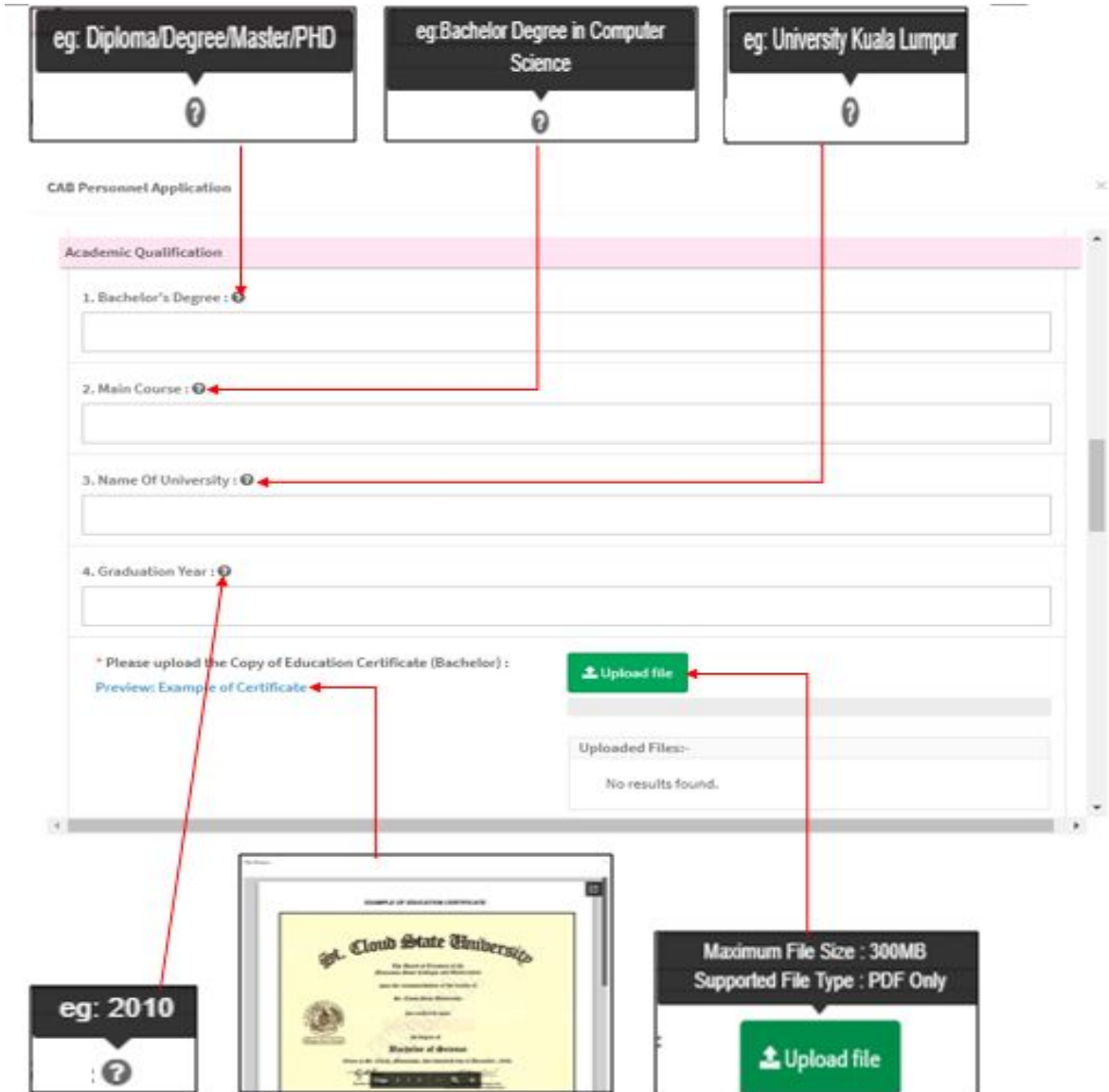
1. Bachelor's Degree

The user should fill the form based the academic qualification of personnel.

The user can see the example of bachelor's degree with clicking . The example are "Diploma/Degree/Master/PHD". User can see the example at the figure below.

2. Main course

The user must fill the course that user qualified. User can see the example of course with click at  and the example will appear. The example can see at figure below.



3. Name of University

The user should fill the form or textbox that provided. User also can see the example of university with clicking at **?** that shown in figure above.

4. Graduation Year

The user need to fill the textbox that provided. The user can see the example year with click at **?** that show in figure above.


- Please upload the Copy of Education Certificate(Bachelor)

The symbol “*” means required field. The user must compulsory to upload the

file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link “[Preview:Example of Certificate](#)” and example form will

appear. Beside that, user can download and print by clicking symbol .

I have a Master's Degree:

- The user should click at radio button “YES” or “NO” . If “NO” the form to fill not displayed. If “YES”, the form for master will be displayed and the user must fill it. The figure below shows the form Master.

2. Master's Degree

The user should fill in the textbox that shown in the figure below.

3. Main Course

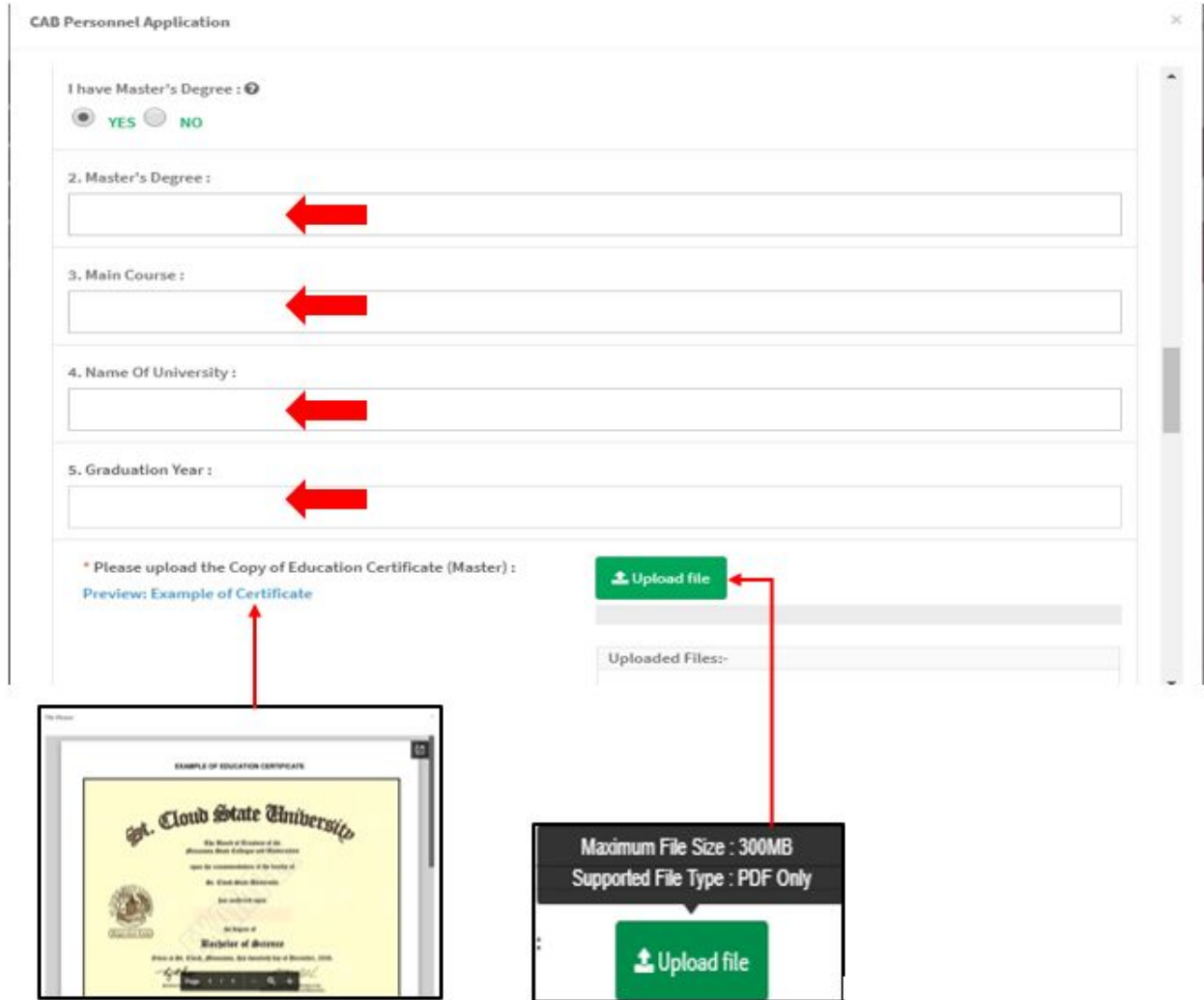
The user should fill in the textbox that shown in the figure below.



4. Name of University

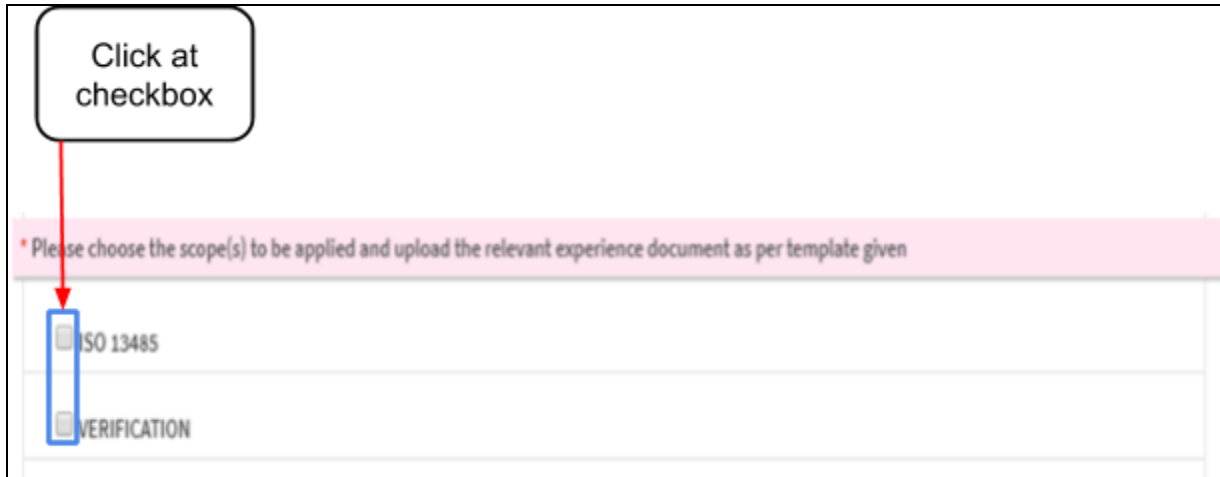
The user should fill in the textbox that shown in the figure below.

5. Graduation Year

The user should fill in the textbox that shown in the figure below.



- Please upload the Copy of Education Certificate(Master)
 The symbol “*” means required field. The user must compulsory to upload the file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link “[Preview: Example of Certificate](#)” and example form will appear. Beside that, user can download and print by clicking symbol .



Please choose the scope(s) to be applied and upload the relevant experience document as per template given.

"ISO 13485" was displayed depend the user choose of scope to be applied.



The symbol "*" is required field. The user must fill the form that are selected. The user should click checkbox "ISO 13485" to fill the form. The "VERIFICATION" also can choose within click in checkbox, if user want to be applied it.

After click in ISO 13485 , the form of ISO will be displayed. The figure below shows the form for "ISO 13485".

2.3 Related work Experiences

- Type

The user should click at textbox field and the dropdown list will display which are "CURRENT WORK" and "PREVIOUS WORK". The user should select one of them that shown in the figure below.

- Business Nature

The user should fill in the textbox that shown in the figure below.

The screenshot shows the 'Related Work Experiences' section of the 'CAB Personnel Application' form. A legend at the top left indicates that the 'CURRENT WORK' section is highlighted in blue. A red box highlights a 'Click to remove field' button (a red square with an 'x') in the top right corner. A dashed purple box encloses the 'Job Description' field, the 'Save Working Experience' button, and the 'Related Work Experiences List' table. Three numbered callouts are present: 1. 'Fill in the textbox field' points to the 'Business Nature' input field. 2. 'Click button to save' points to the 'Save Working Experience' button. 3. 'Detail after fill the form' points to the 'Related Work Experiences List' table. A 'Click for delete' callout points to a red 'x' icon in the top right corner of the table row.

Related Work Experiences Form Fields:

- Type: CURRENT WORK
- Name Of Company: [Textbox]
- Business Nature: [Textbox]
- Total Working Years: [Textbox]
- Position: [Textbox]
- Job Description: [Textbox]

Related Work Experiences List Table:

Name Of Company	Business Nature	Total Working Years	Position	Job Description
SYARIKAT A BERHAD	PROGRAMMING	2 years	PROGRAMMER	1. CODING 2. PROGRAM

- Name of Company

The user should fill in the textbox that shown in figure above.

- Total working years


The user should fill in the textbox that shown in figure above.

- Position

The user should fill in the textbox that shown in figure above.

- Job description

The user should fill in the textbox that shown in figure above. User can add the


job description with click at  and the textbox field will be added that

shown in figure above. The user also can delete the field with click at .

1

- User should fill in description in the textbox field.

2

- User should click at button  to save the experiences and automatically display in list.

3

- The detail that user fills in the form will be displayed at the Related Work Experiences List that are shown in figure above.

ISO 13485 Lead Auditor Training Course / ISO 13485 TRAINING COURSE (MIN 2 DAYS).

The symbol "*" is required field. The form is compulsory to fill it.

- Type of Certificate

The user should click in the textbox field to see the dropdown list. There has four type of certificate which are:


- a) Certificate of proficiency
- b) Certificate of Attendance
- c) Certificate of Completion
- d) Certificate of Participation


The user should select one of them.

- Training date

The user should click at textbox field for "From" and "To" to display the calendar. The user should select the date.

- Please upload the Copy of ISO 13485 Lead Auditor Training Course Certificate
The symbol “*” means required field. The user must compulsory to upload the

file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link “[Preview: Example of Certificate](#)” and example form will

appear. Beside that, user can download and print by clicking symbol .

CERTIFICATE OF PROFICIENCY
 CERTIFICATE OF ATTENDANCE
 CERTIFICATE OF COMPLETION
 CERTIFICATE OF PARTICIPATION

November 2017

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Fill in textbox

CAB Personnel Application

ISO 13485 Lead Auditor Training Course / ISO 13485 TRAINING COURSE (MIN 2 DAYS)

* Type Of Certificate :
 CERTIFICATE OF PROFICIENCY

* Training Date
 From : 2017-11-17 To : 2017-11-17

* Please upload the Copy of ISO 13485 Lead Auditor Training Course Certificate
 Preview: Example of Certificate
 Upload file
 Upload File is Required To Save Training Detail



Training List
 No results found.

Click for Upload File

Total Audit Days
 Total audit-days for ISO 13485 / ISO 9001 certification : 0

Example of Certificate


Training List
 CERTIFICATE OF PROFICIENCY
 Training Date
 From : 2017-11-17
 To : 2017-11-18
 Certificate Copy
 26.3KB.pdf


- Training List
 Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown in figure above. The user can download and delete the certificate with click at  for download and  for delete.

Total audit days

- Total audit-days for ISO 13485 / ISO 9001 certification

The user should fill the provided textbox with number only. If user fill it except

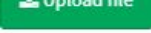
 Saving Failed! Please Check Your Data!

number, the message “” will be displayed. After that, the upload file will be displayed that shown at the figure below.




- Please upload the Copy of ISO 13485's or ISO 9001's Audit Log
User also can preview the example form which is user click the link **“Preview: Example of Certificate”** and example form will appear.

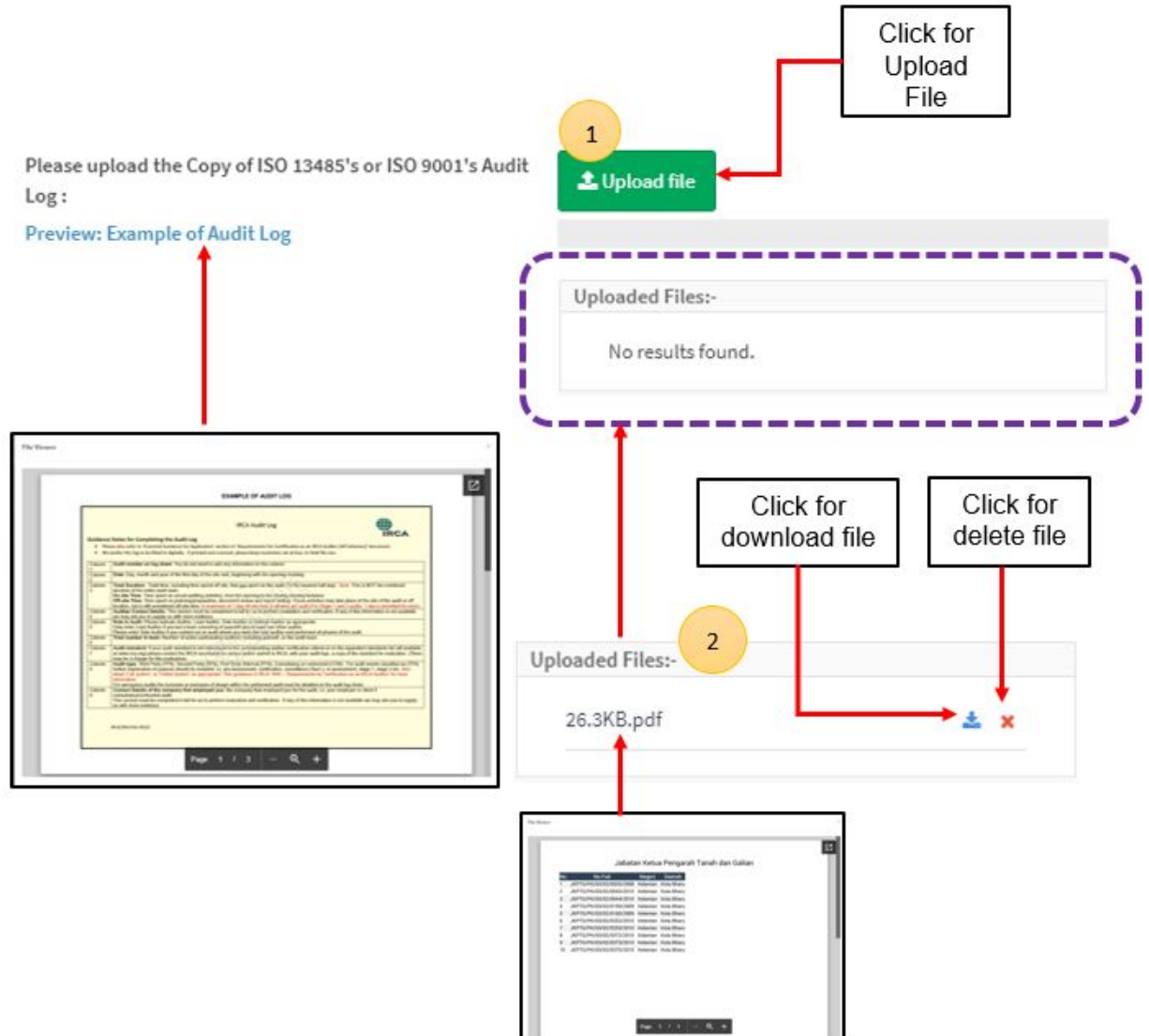
Beside that, user can download and print by clicking symbol .

1

-The user should upload file with click at  that shown at the figure below.

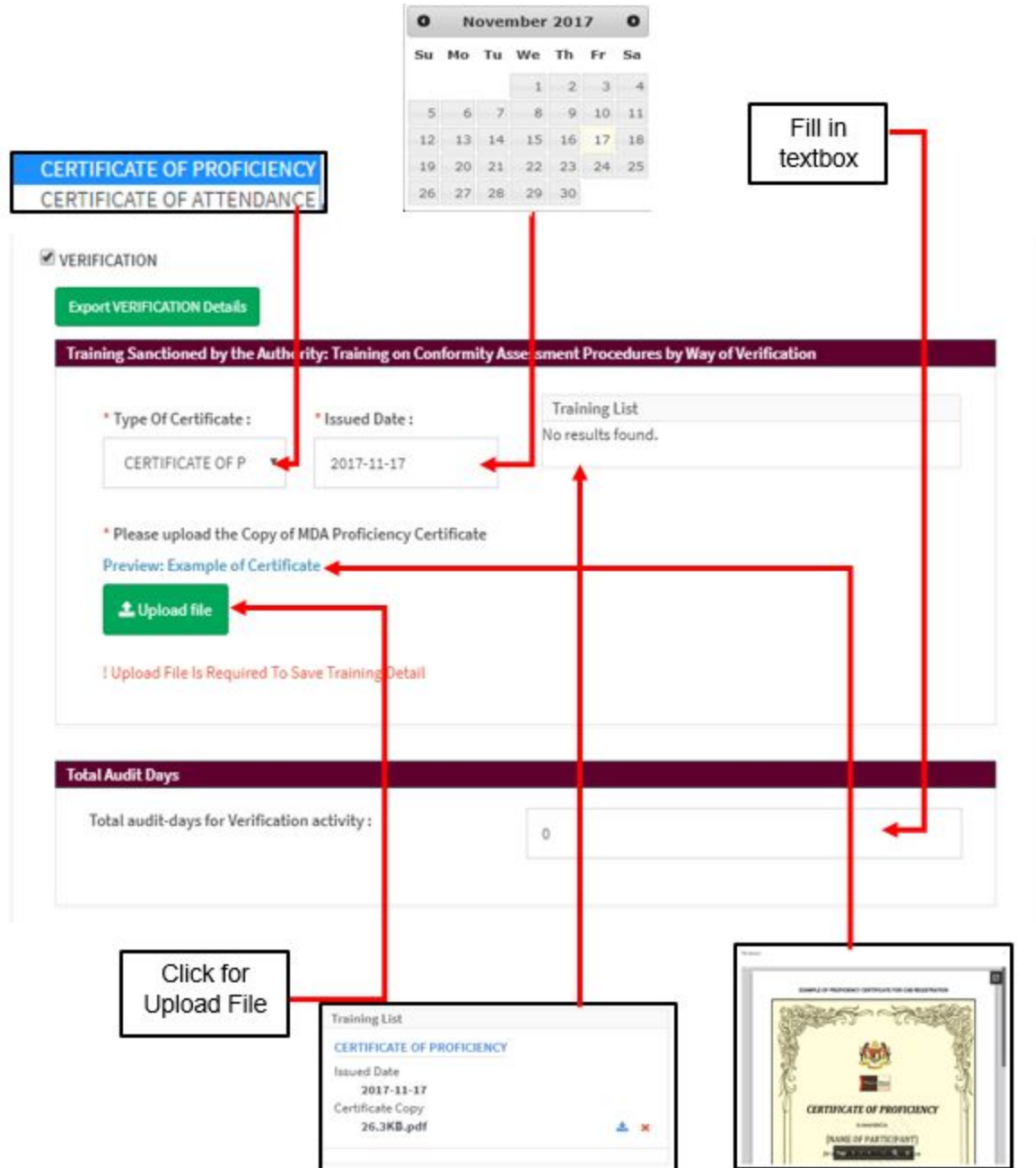
2

- The file that user uploads will be displayed at uploaded files. The user can view the file with click at file name and also can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete.



The user should click for export to word format. It is automatically download the details in word.

For verification: User click at button checkbox VERIFICATION . The form for verification will be displayed.



- Training sanctioned by the authority: Training on conformity assessment procedures by way of verification** (The symbol “*” means required field.)
 - Type of certificate -> the user should select whether CERTIFICATE OF PROFICIENCY or CERTIFICATE OF ATTENDANCE that shown in figure above.

- Issued date -> the user should click at the textbox provided to select the date in calendar that follow with format “yy-mm-dd”.
- Please upload the Copy of MDA Proficiency Certificate -> The user must

compulsory to upload the file. User must click at button





untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link

“[Preview: Example of Certificate](#)” and example form will appear.

Beside that, user can download and print by clicking symbol



- Training list -> Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown in figure above. The user can download and delete the certificate with click at  for download and  for delete.

● **Total Audit Days**

- Total audit-days for Verification activity

The user should fill the provided textbox with number only. If user fill it

except number, the message “

Saving Failed! Please Check Your Data!

” will be displayed. After that, the upload file will be displayed that shown at the figure below.

- Please upload the Copy of Verification’s Audit Log

User also can preview the example form which is user click the link

“[Preview: Example of Audit Log](#)” and example form will appear. Beside

that, user can download and print by clicking symbol




-The user should upload file with click at

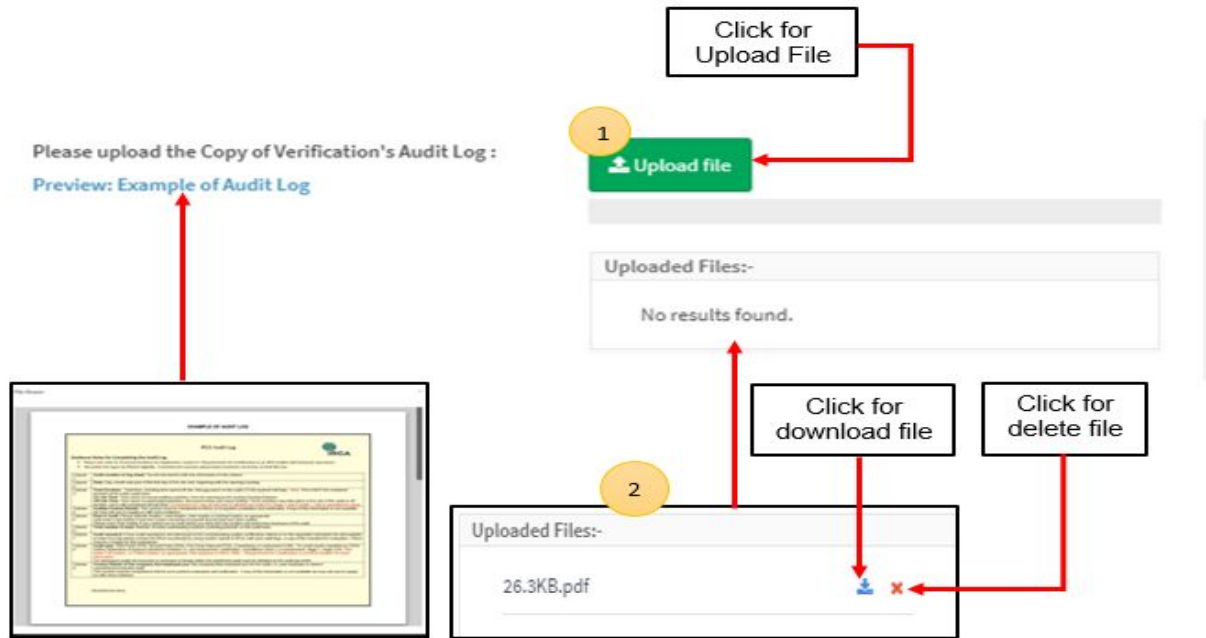




that shown at


figure

below.

- 2 - The file that user uploads will be displayed at uploaded files. The user can view the file with click at file name and also can download and print by clicking symbol .



The user can download and delete the file with click at  for download and  for delete.

The user should click  for export to word format. It is automatically download the details in word.

Other Training Courses

- Related Training Course
- Type of Certificate


The user should click in the textbox field to see the dropdown list. There has four type of certificate which are:

- e) Certificate of proficiency



- f) Certificate of Attendance
- g) Certificate of Completion
- h) Certificate of Participation

The user should select one of them of certificates.

- Issued date -> the user should click at the textbox provided to select the date in calendar that follow with format “yy-mm-dd”.
- Please upload the Copy of MDA Proficiency Certificate -> The user must

compulsory to upload the file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link “[Preview: Example of Certificate](#)” and example form will appear. Beside that, user can download

and print by clicking symbol .

- Training list -> Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown in the figure below. The user can download and delete the certificate with click at  for download and  for delete.

CERTIFICATE OF PROFICIENCY
 CERTIFICATE OF ATTENDANCE
 CERTIFICATE OF COMPLETION
 CERTIFICATE OF PARTICIPATION

November 2017

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

* Other Training Courses

* Training Sanctioned by the Authority : Training on Conformity Assessment Body Registration Under the Act 737

Related Training Course

* Type Of Certificate : CERTIFICATE OF PRC

* Issued Date : 2017-11-18

Training List
 No results found.

* Please upload the Copy of MDA Proficiency Certificate
 Preview: Example of Certificate

Upload file


! Upload File Is Required To Save Training Detail

Click for upload file

Training List
 CERTIFICATE OF PROFICIENCY
 Issued Date
 2017-11-18
 Certificate Copy
 26.3KB.pdf



● **Related Training Course for ISO 14971**

- Type of certificate -> The user should select “CERTIFICATE OF PROFICIENCY” or “CERTIFICATE OF ATTENDANCE”.
- Issued Date -> The user should click at the textbox provided to select the date in calendar that follow with format “yy-mm-dd”.
- Please upload the Copy of ISO 14971 Training Course Certificate -> The user

must compulsory to upload the file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also

can preview the example form which is user click the link “**Preview: Example of Certificate**” and example form will appear. Beside that, user can download

and print by clicking symbol  .

- Training list -> Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown in the figure below. The user can download and delete the certificate with click at  for download and  for delete.

CERTIFICATE OF PROFICIENCY
CERTIFICATE OF ATTENDANCE

November 2017

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Click for upload file

* ISO 14971 Risk Management for Medical Device Training Course :

Related Training Course

* Type Of Certificate :
 CERTIFICATE OF PRC

* Issued Date :
 2017-11-18

Training List
 No results found.

* Please upload the Copy of ISO 14971 Training Course Certificate

Preview: Example of Certificate

Upload file

! Upload File Is Required To Save Training Detail

EXAMPLE OF ISO 14971 TRAINING COURSE CERTIFICATE

ISO 14971 of quality
 [mda] [mda] [mda]

Certificate of Training

Certificate No. _____

This is to certify that _____

has successfully completed training on
 ISO 14971:2007 Medical Devices - Application of
 Risk Management to the Design and Development of Devices

(Date of issue: 11/18/2017)

Training List

CERTIFICATE OF PROFICIENCY

Issued Date
 2017-11-18

Certificate Copy
 26.3KB.pdf

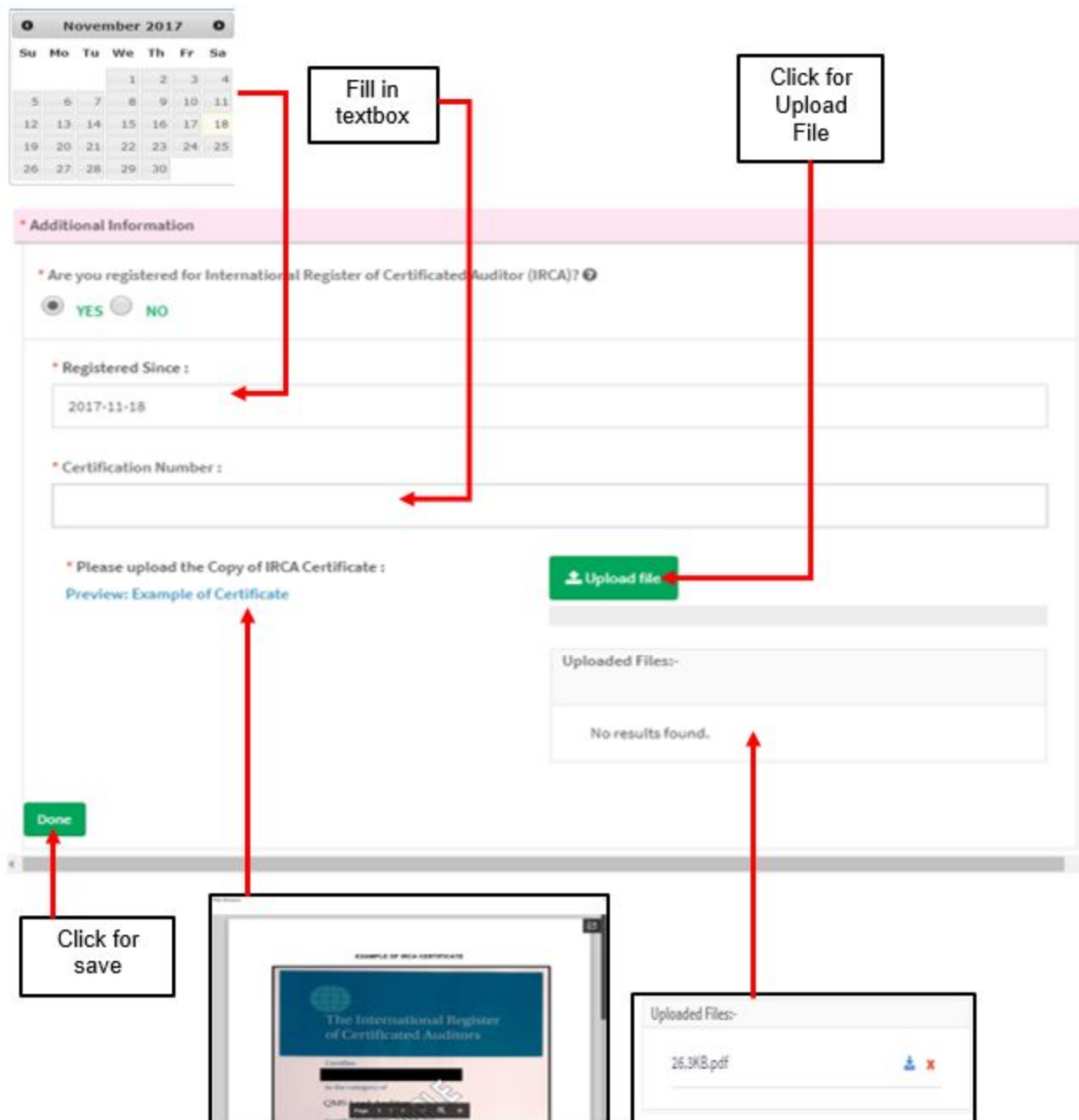
● **Additional Information**

Are you registered for International Register of Certificated Auditor(IRCA)?

-> The user should choose “YES” or “NO” with click at radio button.






If user click on “YES”, the form for “YES” decision will be displayed.



- Registered since -> The user should click at textbox to display the calendar that show in figure above. The user should select the date in calendar that provided. The format is "yyyy-mm-dd".
- Certification Number -> the user should fill the textbox with number of certificate.

- Please upload the Copy of IRCA Certificate -> The user must compulsory to

upload the file. User must click at button  untuk upload file PDF only and not more than 300MB for file size. The user can download and delete the file with click at  for download and  for delete. User also can preview the example form which is user click the link "[Preview: Example of Certificate](#)" and example form will appear. Beside that, user can download

and print by clicking symbol .

- After all form was filled, the user should click button "DONE" that shown in figure above.


If user want to choose "GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES(GDPMD)+POST-MARKET SURVEILLANCE SYSTEM" or "MEDICAL DEVICE TECHNICAL AREAS", the user should click in the checkbox like shown in the figure below.



2.1 Information on the Scope(s) to be Applied

- ISO 13485 + POST-MARKET SURVEILLANCE SYSTEM
- GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD) + POST-MARKET SURVEILLANCE SYSTEM
- MEDICAL DEVICE TECHNICAL AREAS

Click in Checkbox

After that, user should click again button  for add the personnel.

The form for personnel will displayed.

* Please choose the scope(s) to be applied and upload the relevant experience document as per template given

GDPMD

[Export GDPMD Details](#)

Related Work Experiences

* Type :
 CURRENT WORK

* Name Of Company :

* Business Nature :

* Total Working Years :

* Position :

* Job Description :

[Save Working Experience](#)

Related Work Experiences List				
CURRENT WORK				
Name Of Company	Business Nature	Total Working Years	Position	Job Description
DAS SDN BHD	PROGRAMMING	3 years	MANAGER	1. RESPONSIBLE TO LEAD

1 Fill in the textbox field

2 Click button to save

3 Detail after fill the form



Click to remove field

Click for delete

- Please choose the scope(s) to be applied and upload relevant experience document as per template given.

- 1) GDPMD
 - Related work experiences


- Type -> The user should click in the textbox and the dropdown list will be displayed. User should select "CURRENT WORK" or "PREVIOUS WORK".
- Business Nature -> The user should fill the textbox that provided.
- Name of Company -> the user should fill the textbox that provided.
- Total working years -> The user should fill in the textbox that shown in figure above.
- Position ->The user should fill in the textbox that shown in figure above.
- Job description

The user should fill in the textbox that shown in figure above. User can add the job description with click at  and the textbox field will be added that shown in figure above. The user can also delete the field with click at .

1

- User should fill in the textbox field.

2

- User should click at button  to save the experiences and automatically display in list.

3

- The detail that user fills in the form will be displayed at the Related Work Experiences List that are shown in the figure above.

CERTIFICATE OF PROFICIENCY
CERTIFICATE OF ATTENDANCE

November 2017

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

ISO 9001 Lead Auditor Training Course

* Type Of Certificate :
 CERTIFICATE OF PROFICIENCY

* Training Date
 From: 2017-11-18 To: 2017-11-18

* Please upload the Copy of Attended Training Course Certificate Related to this Scope
 Preview: Example of Certificate
 Upload file

! Upload File Is Required To Save Training Detail

Training List
 CERTIFICATE OF PROFICIENCY
 Training Date
 From: 2017-11-19
 To: 2017-11-19
 Certificate Copy
 26.3KB.pdf

Training List
 No results found.

Total Audit Days

Total audit-days for ISO 9001 certification : 0

Click for Upload File


Total audit-days for ISO 9001 certification : 1
 Please upload the Copy of ISO 9001's Audit Log:
 Preview Example of Audit Log
 Upload file
 Uploaded Files:
 No results found.

● **ISO 9001 Lead Auditor Training Course**



- Type of certificate -> The user should select “CERTIFICATE OF PROFICIENCY” or “CERTIFICATE OF ATTENDANCE”.
- Training date -> The user should click at textbox “FROM” and “TO” that provided to select the date in calendar that follow with format “yy-mm-dd”.

- Please upload the Copy of Attended Training Course Certificate Related to this scope -> The user must compulsory to upload the file. User must click at



button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link "**Preview: Example of Certificate**" and example form will appear. Beside that,


user can download and print by clicking symbol .

- Training list -> Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown in figure above. The user can download and delete the certificate with click at  for download and  for delete.

- **Total Audit Days**

- Total audit-days for ISO 9001 certification

The user should fill the provided textbox with number only. If user fill it

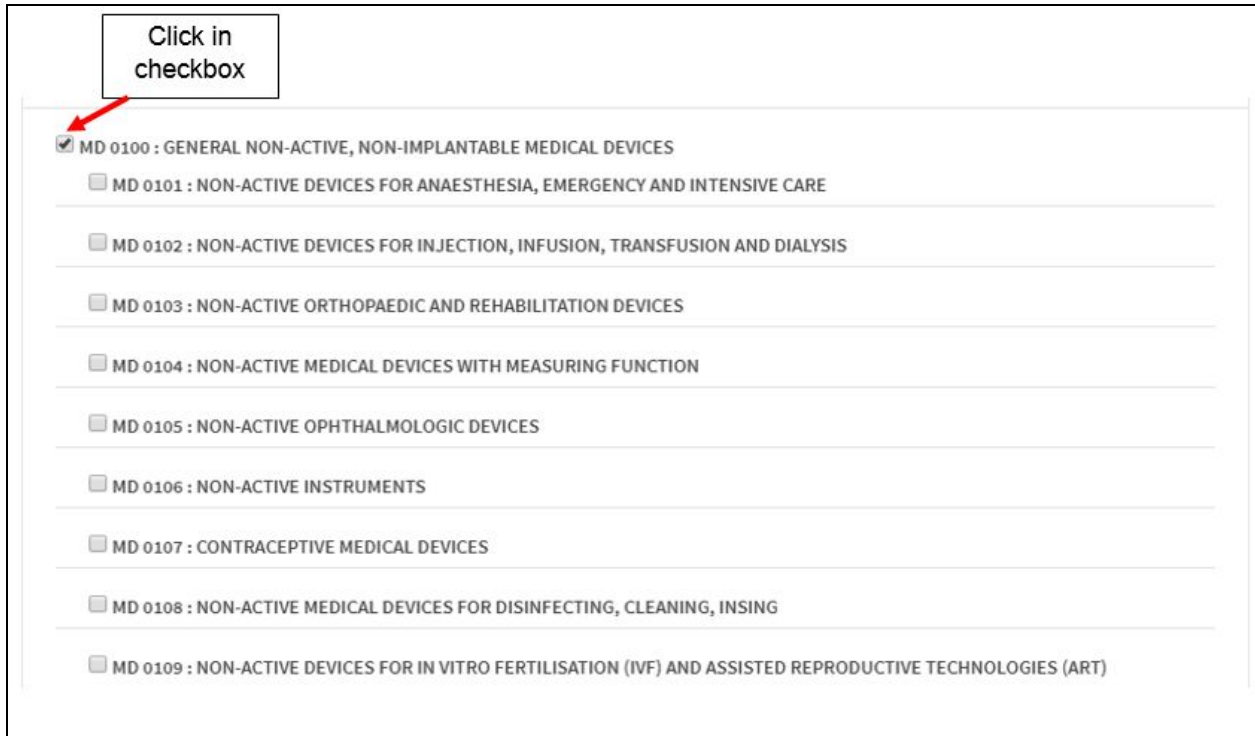
except number, the message "" will be displayed. After that, the upload file will be displayed that shown at the figure above.

- Please upload the Copy of ISO 9001's Audit Log

The user should upload file with click at button "Upload file". User also can preview the example form which is user click the link "**Preview: Example of Audit Log**" and example form will appear.

The user should click  for export to word format. It is automatically download the details in word.

The user also can choose "MD" type that user wants with click at check button that are provided. The example one of "MEDICAL DEVICE TECHNICAL AREA" that are chooses in the figure below.



Click in checkbox

MD 0100 : GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES

MD 0101 : NON-ACTIVE DEVICES FOR ANAESTHESIA, EMERGENCY AND INTENSIVE CARE

MD 0102 : NON-ACTIVE DEVICES FOR INJECTION, INFUSION, TRANSFUSION AND DIALYSIS

MD 0103 : NON-ACTIVE ORTHOPAEDIC AND REHABILITATION DEVICES

MD 0104 : NON-ACTIVE MEDICAL DEVICES WITH MEASURING FUNCTION

MD 0105 : NON-ACTIVE OPHTHALMOLOGIC DEVICES

MD 0106 : NON-ACTIVE INSTRUMENTS

MD 0107 : CONTRACEPTIVE MEDICAL DEVICES

MD 0108 : NON-ACTIVE MEDICAL DEVICES FOR DISINFECTING, CLEANING, INSING

MD 0109 : NON-ACTIVE DEVICES FOR IN VITRO FERTILISATION (IVF) AND ASSISTED REPRODUCTIVE TECHNOLOGIES (ART)

The user should click in checkbox that are provided. The figure above show the example medical device that chosen. The user clicks in the checkbox “MD 0100:GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES”. The type of medical device under “MD 0100” will be displayed. The user should click one or more than one type of medical device with click in checkbox that provided.

The user choose the type of medical device which is “MD 0101:NON-ACTIVE DEVICES FOR ANAESTHESIA, EMERGENCY AND INTENSIVE CARE”. The user should click in the checkbox that shown in figure below.

Click in checkbox

Click to remove field

Export MD 0101 Details

Related Work Experiences

* Type :
CURRENT WORK

* Name Of Company :

* Business Nature :

* Total Working Years :

* Position :

* Job Description +

Save Working Experience

Related Work Experiences List

PREVIOUS WORK

Name Of Company	Business Nature	Total Working Years	Position	Job Description
ADIDAS SDN BHD	COMPUTER	2 years	MANNAGER	1. RESPONSIBLE FOR LEAD

1 Fill in the textbox field



2 Click button to save

3 Detail after fill the form

Click for delete

● **Related work Experiences**

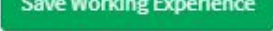
- Type -> The user should click in the textbox and the dropdown list will be displayed. User should select "CURRENT WORK" or "PREVIOUS WORK".
- Business Nature -> The user should fill the textbox that provided.
- Name of Company -> the user should fill the textbox that provided.

- Total working years -> The user should fill in the textbox that shown in figure above.
- Position ->The user should fill in the textbox that shown in figure above.
- Job description -> The user should fill in the textbox that shown in figure above. User can add the job description with click at  and the textbox field will be added that shown in figure above. The user can also delete the field with click at .

1

- User should fill in the textbox field.

2

- User should click at button  to save the experiences and automatically display in list.

3

- The detail that user fills in the form will be displayed at the Related Work Experiences List that are shown in the figure above.

- **Related Training Course for this Scope**

- Type of certificate -> The user should select “CERTIFICATE OF PROFICIENCY” or “CERTIFICATE OF ATTENDANCE”.
- Training date -> The user should click at textbox “FROM” and “TO” that provided to select the date in calendar that follow with format “yy-mm-dd”.
- Please upload the Copy of Attended Training Course Certificate Related to this scope -> The user must compulsory to upload the file. User must click at



button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the example form which is user click the link

“[Preview: Example of Certificate](#)” and example form will appear. Beside that,

user can download and print by clicking symbol .

- Training list -> Training list will be displayed the detail when user fill the form and upload file. Automatically, the list will be displayed that shown


in the figure below. The user can download and delete the certificate

with click at  for download and  for delete.

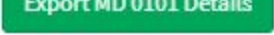
The screenshot displays the 'Related Training Course for this Scope' section. At the top, there is a calendar for November 2017 and a 'Training List' box showing 'CERTIFICATE OF PROFICIENCY' with training dates from 2017-11-19 to 2017-11-19 and a file '26.3KB.pdf'. Below this, the 'Type Of Certificate' is set to 'CERTIFICATE OF PROFICIENCY'. The 'Training Date' is set from 2017-11-18 to 2017-11-18. A message states: '* Please upload the Copy of Attended Training Course Certificate Related to this Scope'. There is a 'Preview: Example of Certificate' link and an 'Upload file' button. A callout box 'Click for Upload File' points to the 'Upload file' button. Below this is the 'Total Audit Days' section, showing 'Total audit-days for this Scope : 0'. A callout box shows a preview of a certificate and an 'Upload file' button with a file list containing '26.3KB.pdf'.


- **Total Audit Days**
 - Total audit-days for this scope

The user should fill the provided textbox with number only. If user fill it

except number, the message “” will be displayed. After that, the upload file will be displayed that shown at the figure above.

- Please upload the Copy of Audit Log Related to this scope:
The user should upload file with click at button “Upload file”. User also can preview the example form which is user click the link “**Preview: Example of Audit Log**” and example form will appear.

The user should click  for export to word format. It is automatically download the details in word.

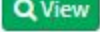
After user fill all the form, the user should click at button  to save the details. The user will see the list of personnel that are filled.

The screenshot displays the 'APPLICATION DETAILS' section on the left, which includes fields for Personnel Details, Bachelor's Degree Details, Master's Degree Details, Personnel Scope(s) To Be Applied, Other Training Courses, and Additional Information, each with a 'Complete' button. Below this is a 'REGISTRATION OF PERSONNEL' section with a green button. A table lists three personnel registration items. The first item is highlighted with a red box, and a red arrow points from a 'Click for update' text box to its 'Update' button. Another red arrow points from the 'Delete' button of the first item to a 'Delete personnel confirmation?' dialog box, which has 'Cancel' and 'OK' buttons.

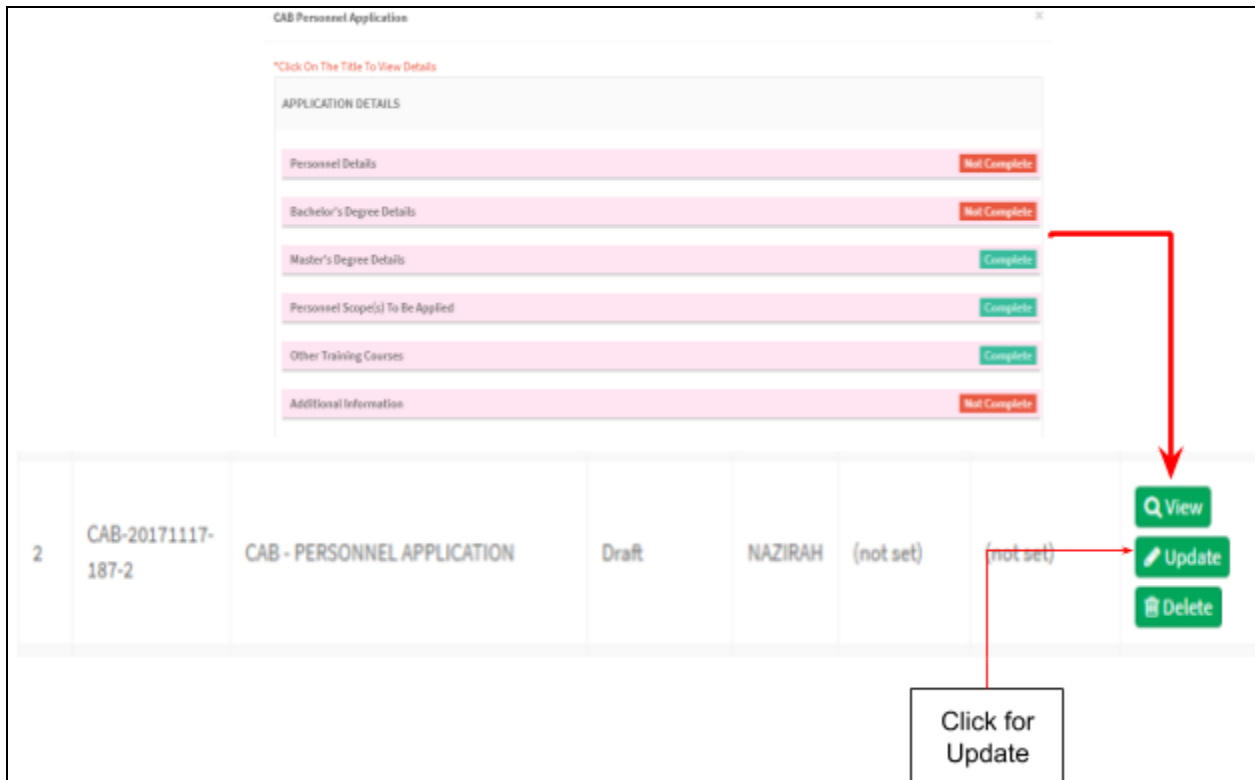
No	Submission ID	Application Type Name	Application Status	Created By	Personnel Name	Personnel Nric	Actions
1	CAB-20171117-187-1	CAB - RE-REGISTRATION PERSONNEL APPLICATION	Filled	NAZIRAH	NAZIRAH NASIR	940106025370	View, Update, Delete
2	CAB-20171117-187-2	CAB - PERSONNEL APPLICATION	Draft	NAZIRAH	(not set)	(not set)	View, Update, Delete
3	CAB-20171117-187-3	CAB - PERSONNEL APPLICATION	Draft	NAZIRAH	(not set)	(not set)	View, Update, Delete

The list of personnel will display in column which are:


- a) Submission ID
- b) Application Type Name
- c) Application status
- d) Created by
- e) Personnel name
- f) Personnel Nric

The user should click at button  to display the detail of personnel. If application status is “Filled”, the view that display is “Complete” that shown in figure above.

If application status is “Draft”, the view that display is “Not Complete”.



The user should update detail again for complete the personnel. If user want to




delete the personnel, the user should click at button  that shown in figure above. The alert confirmation will be displayed which is “Delete personnel confirmation?”. The user can click at “OK” for proceed to delete or “Cancel” to cancel the delete.

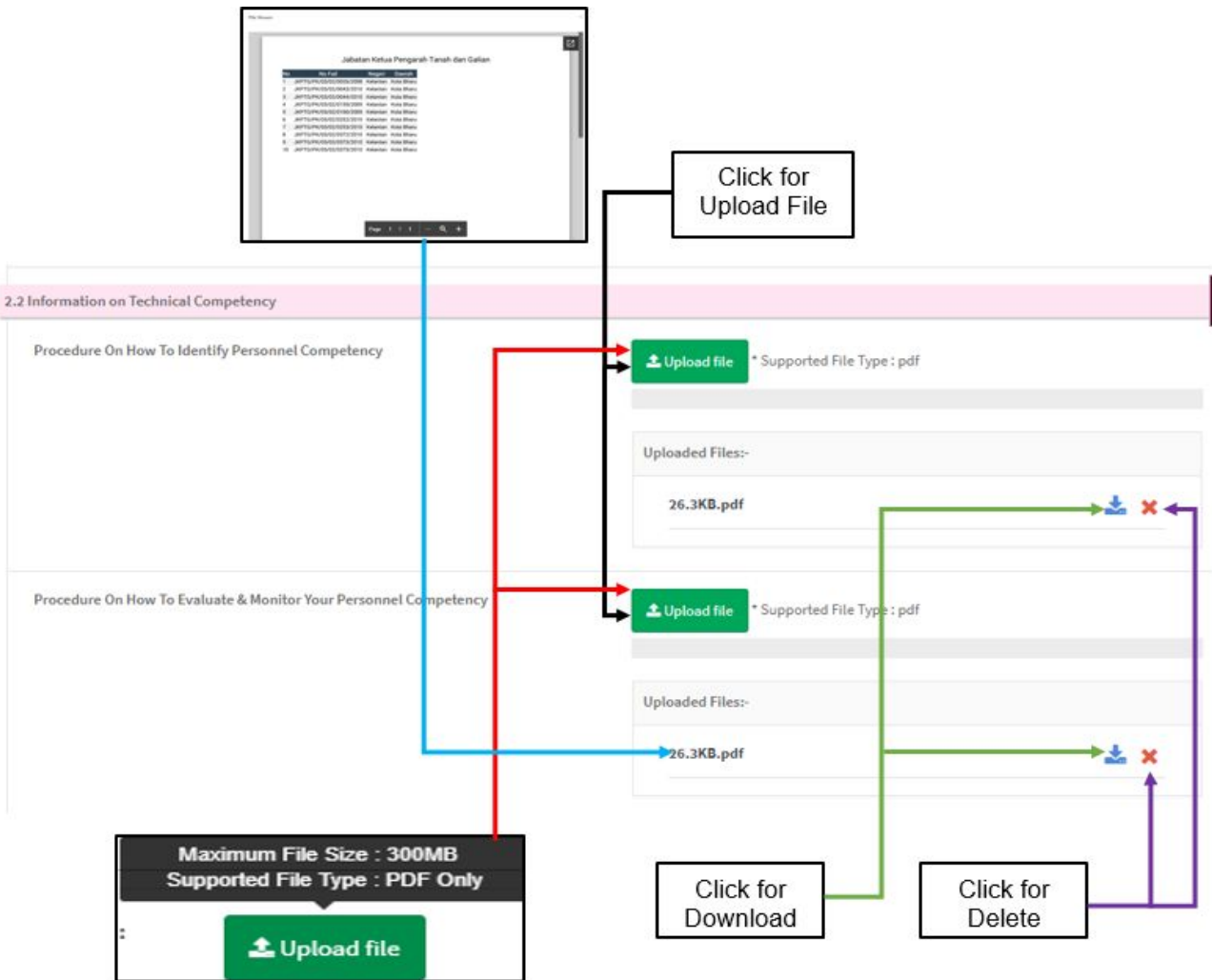
2.4 Information on Technical Competency


- Procedure on How to Identify Personnel Competency -> User must click at




button  untuk upload file PDF only and not more than 300MB for

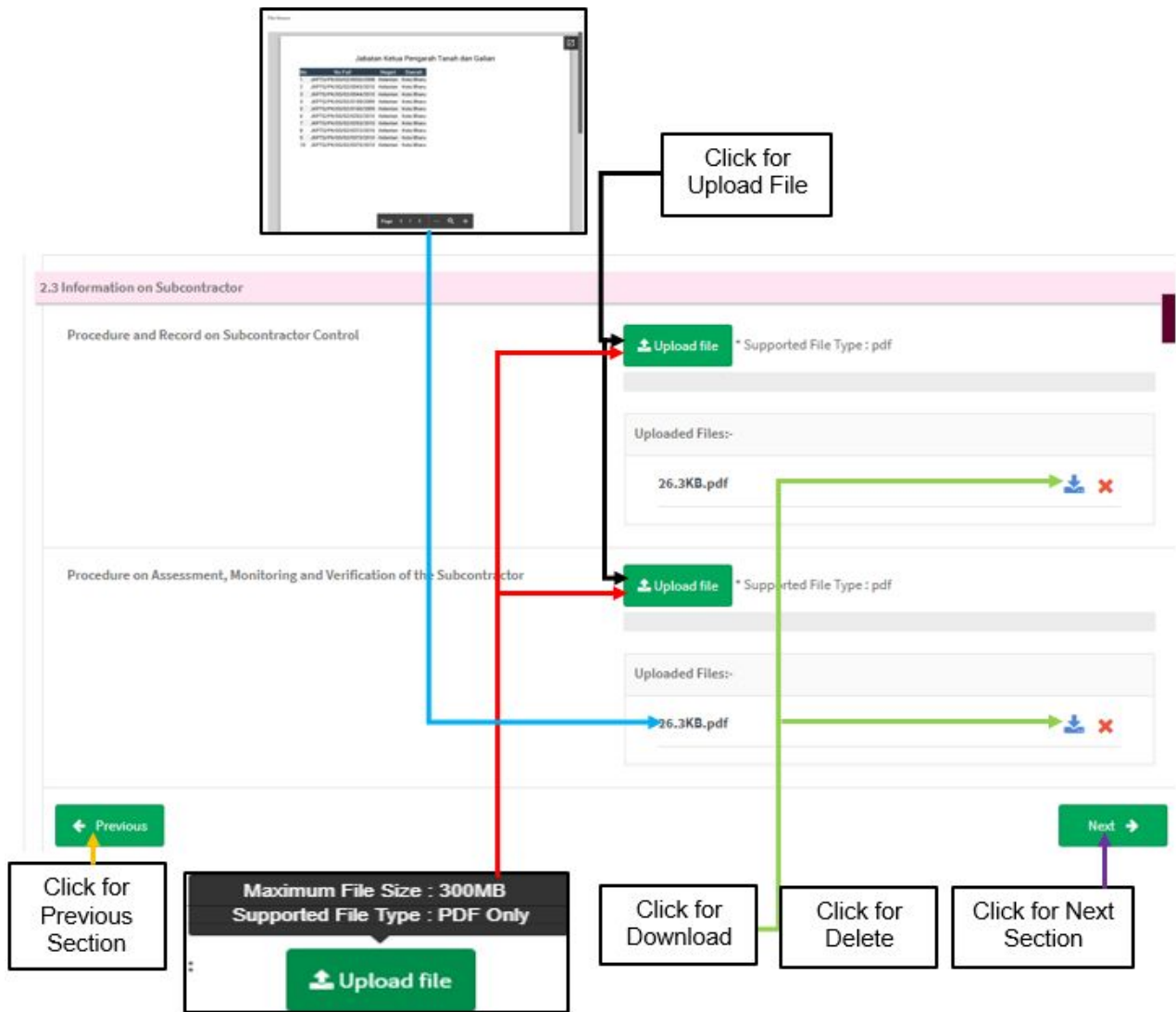
file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking

symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.




- Procedure on How to Evaluate & Monitor Your Personnel Competency -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and

print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in figure above.





2.3 Information on Subcontractor

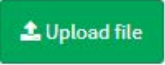
- Procedure and Record on Subcontractor Control -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file

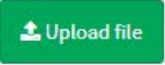
will appear. Beside that, user can download and print by clicking symbol




. The user can download and delete the file with click at  for download and  for delete that shown in figure above.

- Procedure on Assessment, Monitoring and Verification of the Subcontractor ->


 Upload file

User must click on button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and



print by clicking symbol  . The user can download and delete the file


with click at  for download and  for delete that shown in figure above.

If user want to back to the previous section, the user should click on button

 Previous

and that go to section "1.0 REQUIREMENTS ON ORGANIZATION".


 Next 


After form section 2.0 complete fill, the user should click button  and go to section 3.0 "REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY".



Section 3.0 Requirements on independence and impartiality

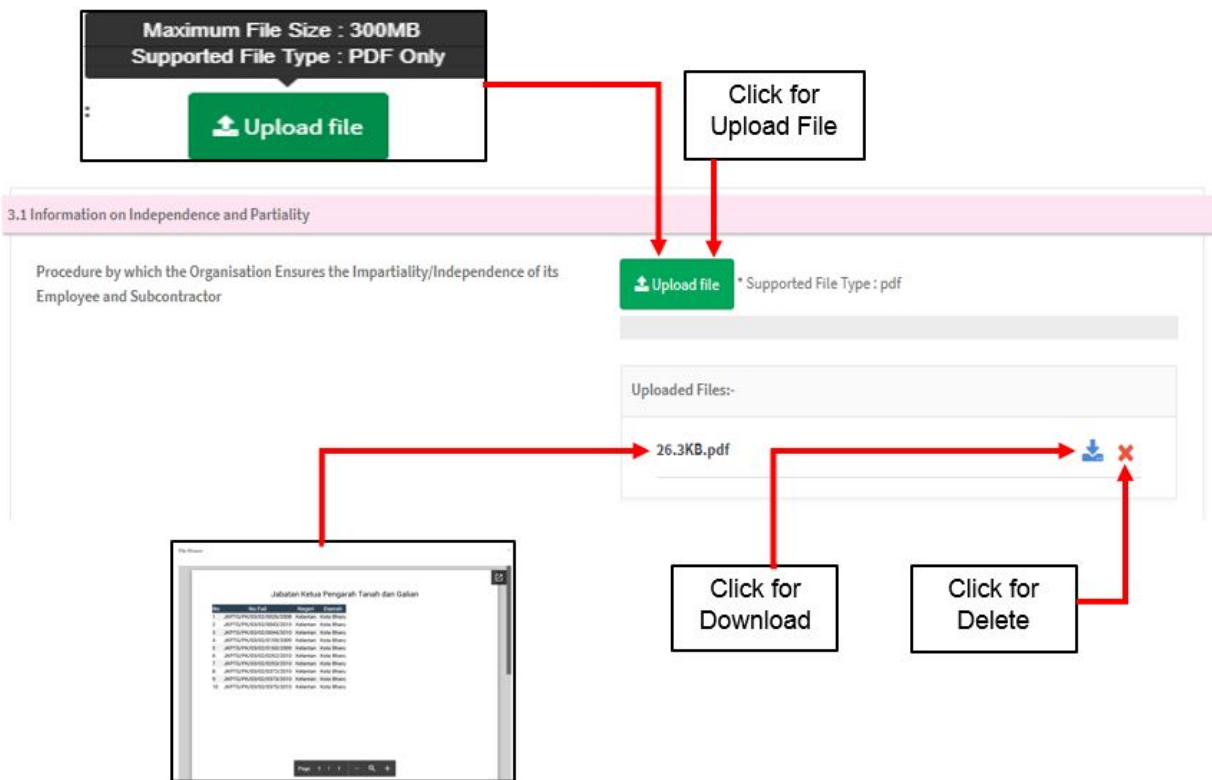
3.1 Information on Independence and Partiality

- Procedure by which the Organisation Ensures the Impartiality/Independence


of its Employee and Subcontractor -> User must click on button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will




appear. Beside that, user can download and print by clicking symbol  .

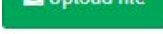
The user can download and delete the file with click at  for download and  for delete that shown in the figure below.






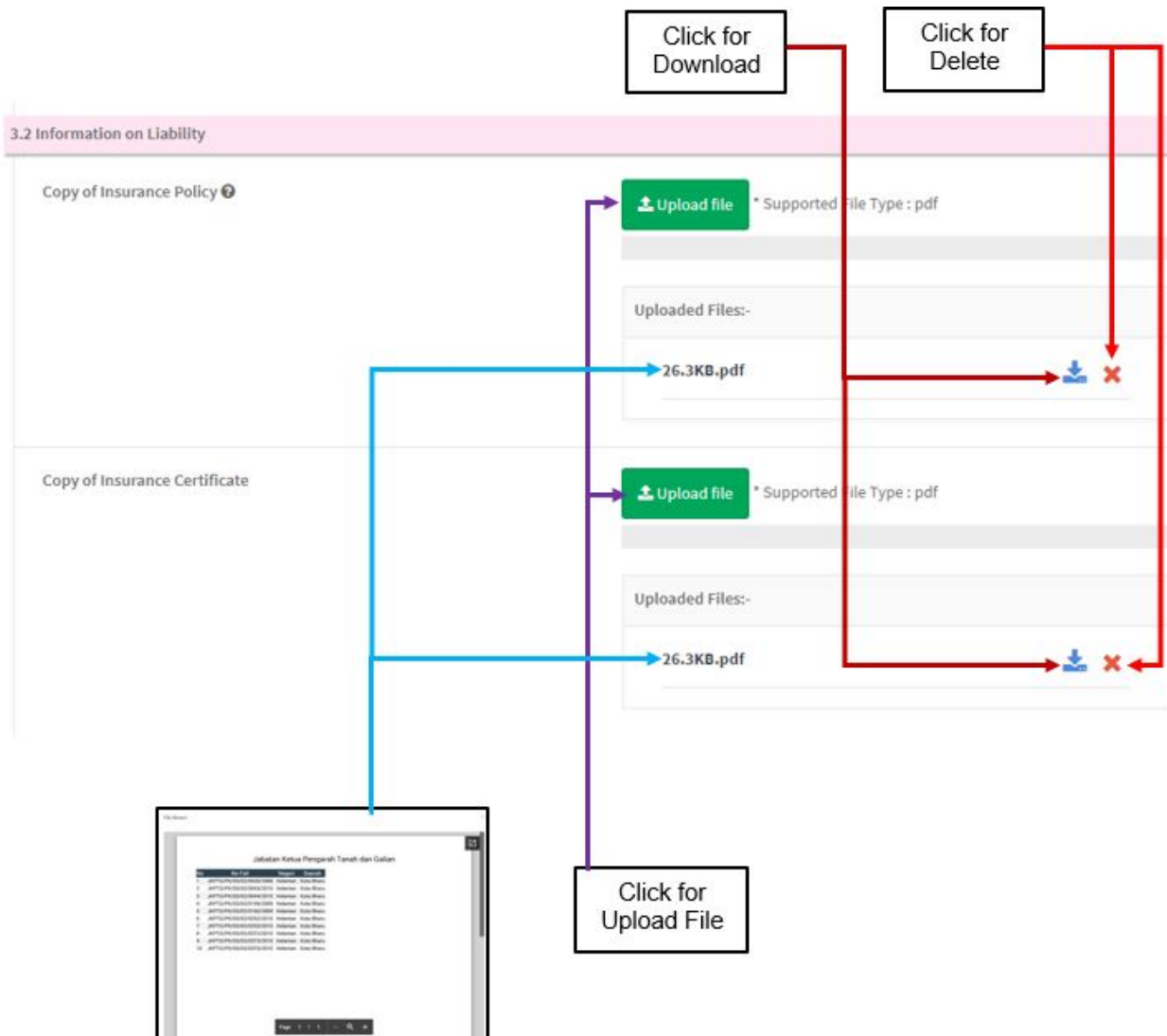
3.2 Information on Liability

- Copy of Insurance Policy -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear.

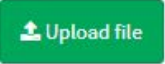
Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.

- Copy of Insurance Certificate -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear.




Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



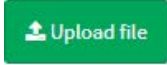
3.3 Information on Confidentiality




- Procedure on maintained the Confidentiality between the Organisation and the Client -> User must click on button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file

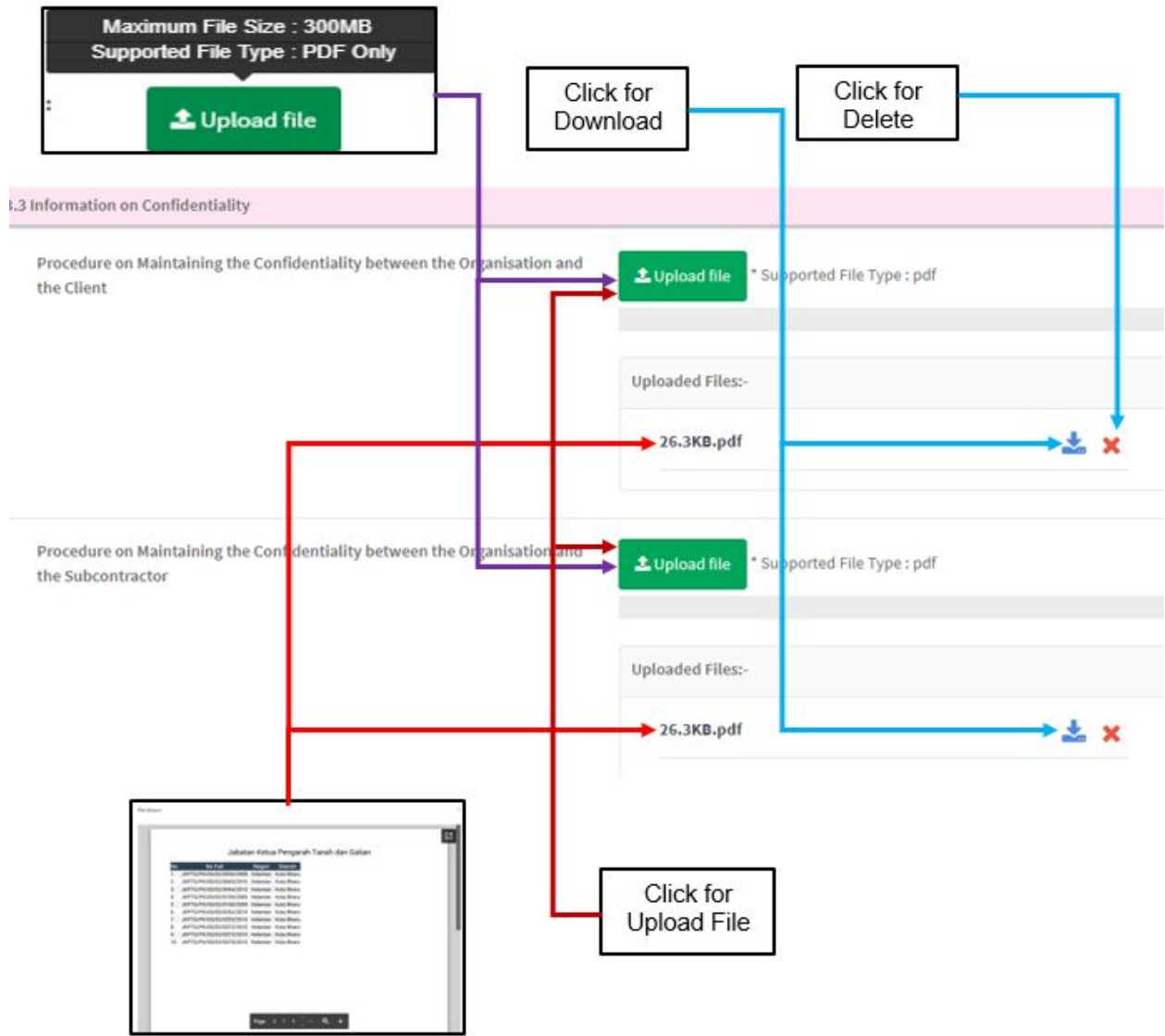
which is user click the link file name and the file will appear. Beside that, user

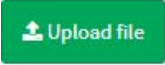



can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.

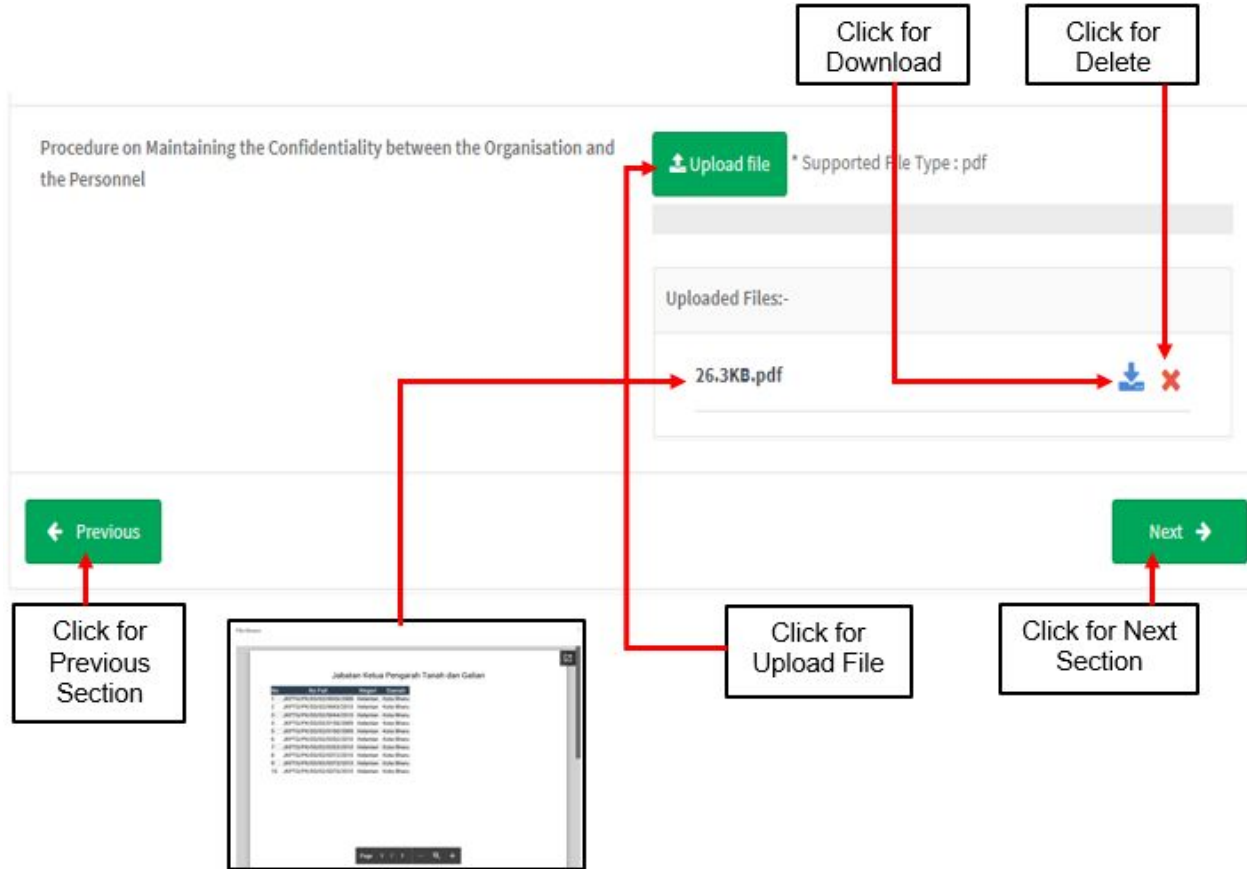
- Procedure on maintained the Confidentiality between the Organisation and

the Subcontractor -> User must click on button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user


can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



- Procedure on maintained the Confidentiality between the Organisation and the Personnel -> User must click on button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.




If user want to back to section 2.0 REQUIREMENTS ON RESOURCES AND

TECHNICAL AND COMPETENCY, the user should click on button  that shown in figure above. If the user want to next section, the user should click on



button  that shown in figure above.


Section 4.0 Requirements on quality management system.

4.1 Documentation related to Management Operation



- Management Quality Manual -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol




. The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



- Procedure on Document Control -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol



. The user can download and delete the file with click at  for download and  for delete that shown in the figure below.

- Procedure on Record Control -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol






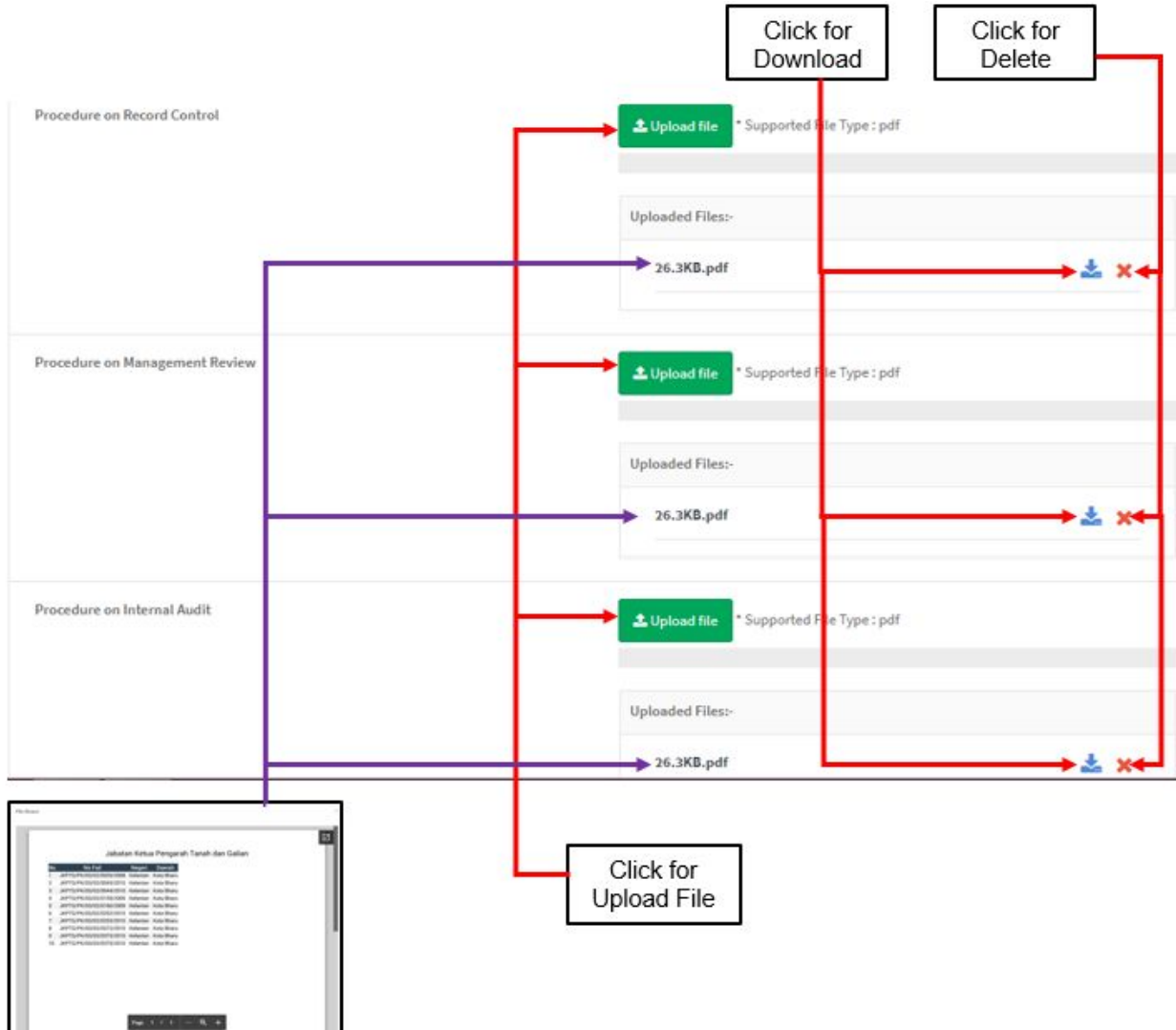
. The user can download and delete the file with click at  for download and  for delete that shown in the figure below.


- Procedure on Management Review -> User must click at button










untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by

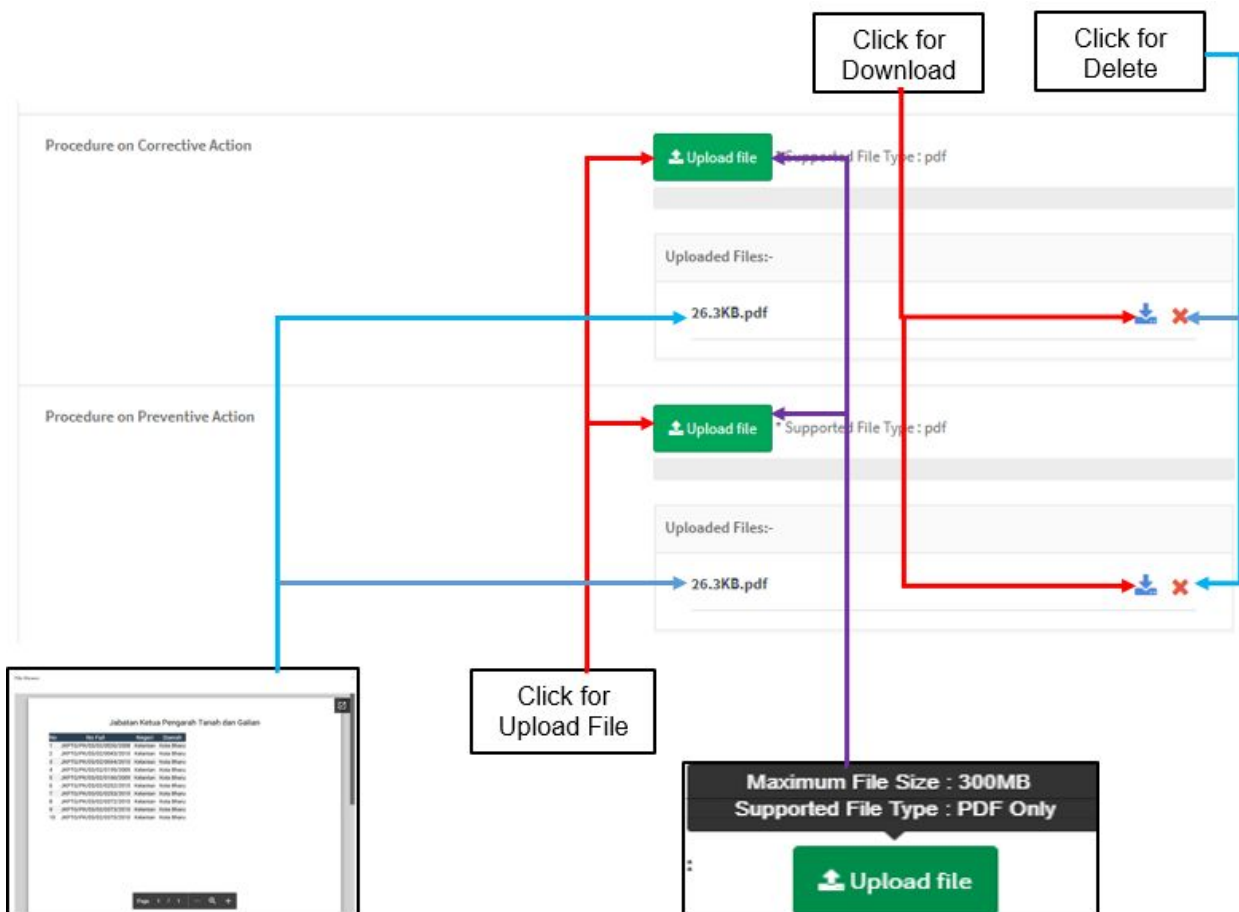
clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.




- Procedure on Internal Audit -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear.



Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in figure above.

- Procedure on Corrective Action -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.




- Procedure on Preventive Action -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will



appear. Beside that, user can download and print by clicking symbol .


The user can download and delete the file with click at  for download and  for delete that shown in figure above.

4.2 Documentation related to Conformity Assessment



- Procedure on Sales and Marketing -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will

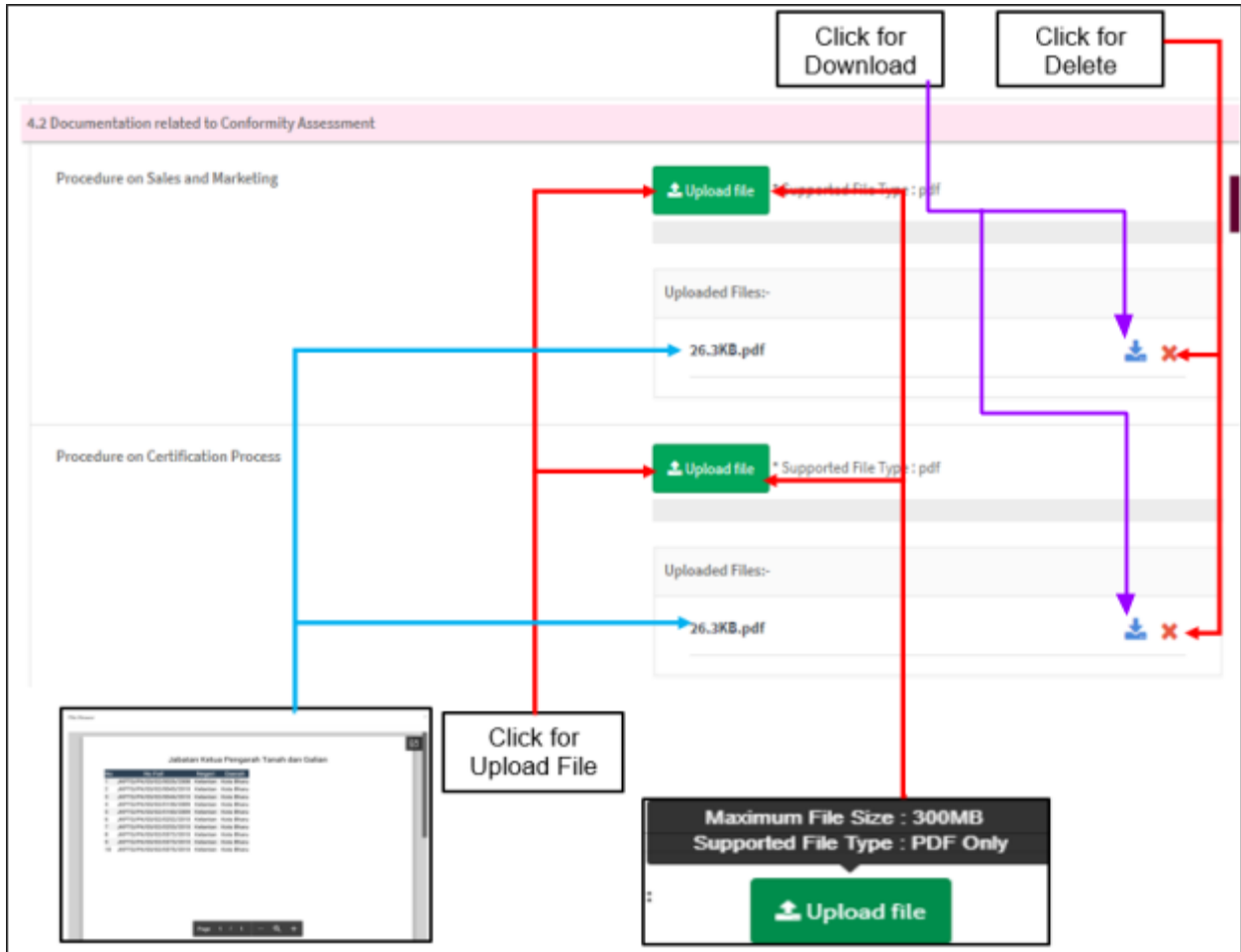
appear. Beside that, user can download and print by clicking symbol .

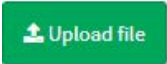




The user can download and delete the file with click at  for download and  for delete that shown in the figure below.

- Procedure on Certification Process -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will



appear. Beside that, user can download and print by clicking symbol .

The user can download and delete the file with click at  for download and  for delete that shown in the figure below.





- Procedure on Transfer of Certificate -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol  . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.
- Procedure on Appeal, Complaint & Dispute -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol






. The user can download and delete the file with click at  for download and  for delete that shown in the figure below.

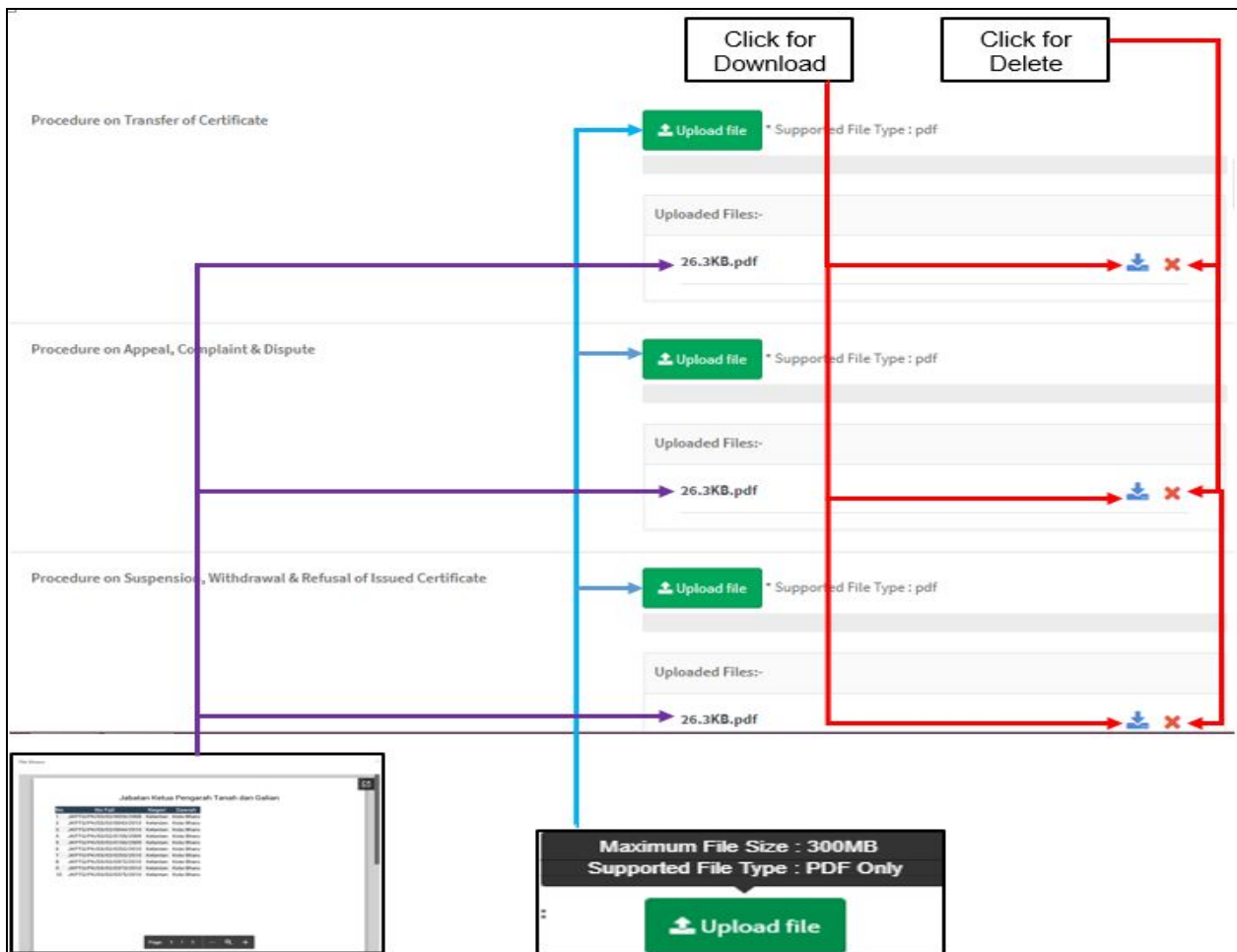
- Procedure on Suspension, Withdrawal & Refusal of Issued Certificate -> User





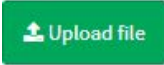



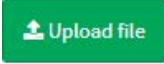



 Upload file

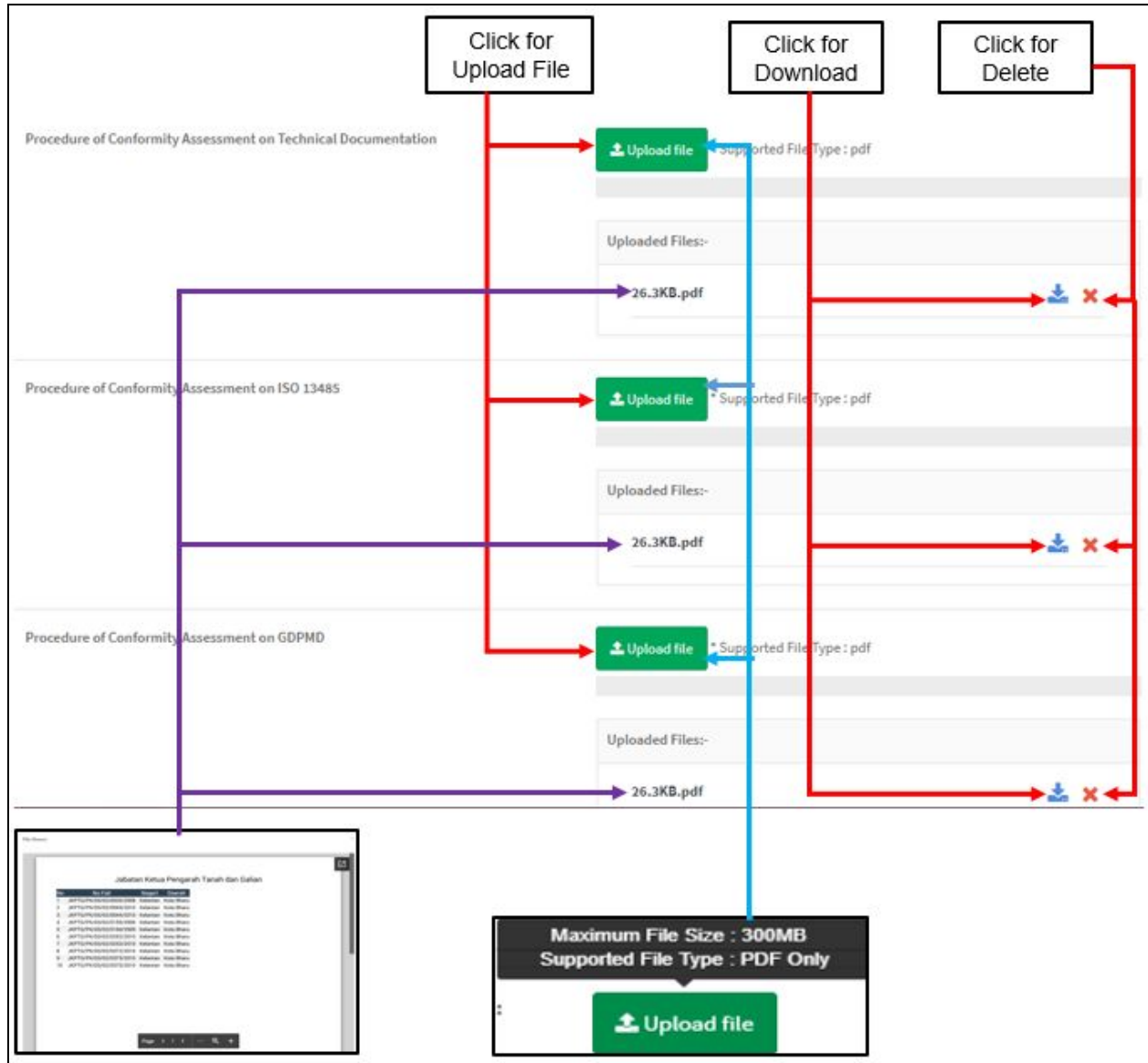
must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and








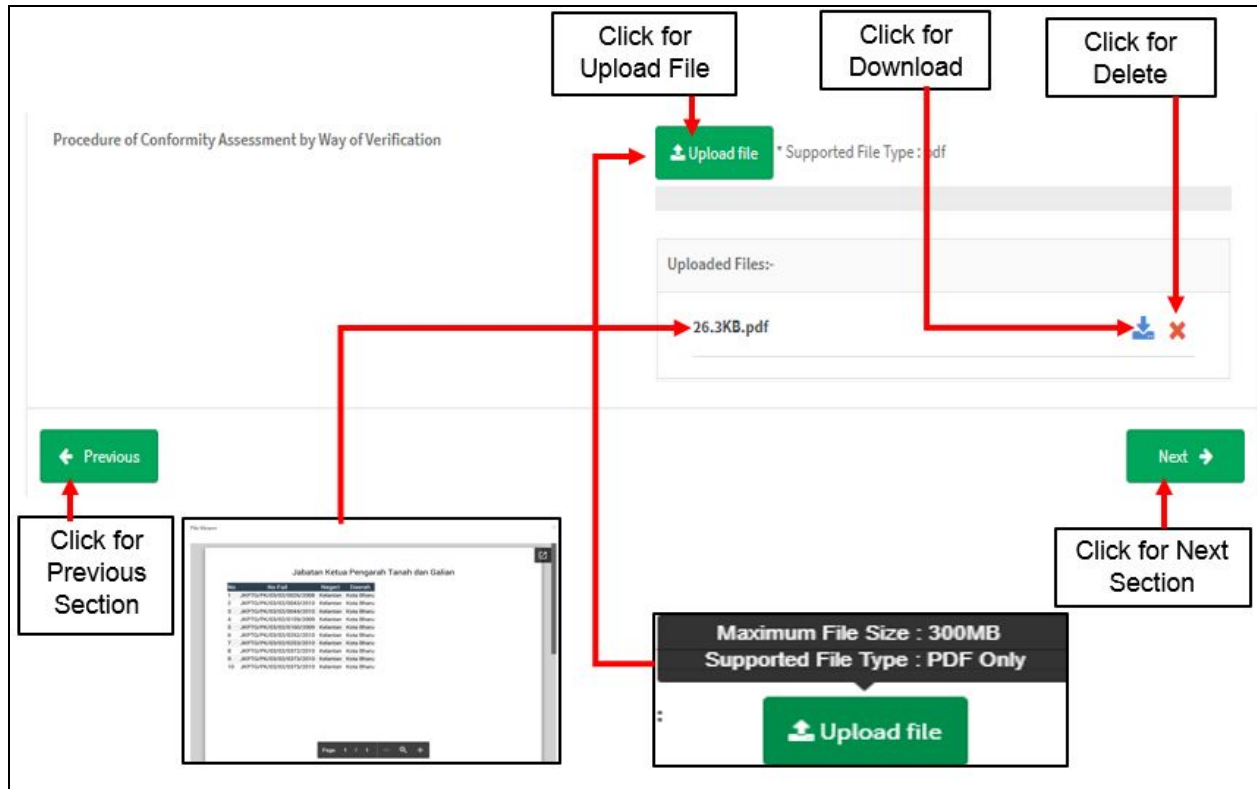
print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



- Procedure of Conformity Assessment on Technical Management -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.
- Procedure of Conformity Assessment on ISO 13485 -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.
- Procedure of Conformity Assessment on GDPMD -> User must click at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.




- Procedure of Conformity Assessment by Way of Verification -> User must click  at button  untuk upload file PDF only and not more than 300MB for file size. User also can preview the file which is user click the link file name and the file will appear. Beside that, user can download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



If user want to back to section 3.0 REQUIREMENTS ON INDEPENDENCE AND

IMPARTIALITY, the user should click at button  that shown in figure

above. If the user want to next section, the user should click at button  that shown in figure above.

Section 5.0 Attestation

5.1 Attestation by Person Responsible

The user must click on radio button that shown in the figure below to accept rules and regulations.

5.1 Attestation by Person Responsible

Date : 18-11-2017

Dear Chief Executive,

ATTESTATION FOR CAB APPLICATION

Person Responsible Name :

NURUL NAZIRAH MOHAMAD NASIR

Person Responsible Identity Card Number :

940106025370

hereby attest that the information provided on this application and any attached documents or certificates which had been duly certified true copy are accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

IMPORTANT: Please read the Medical Device Act 2012 (Act 737) & Medical Device Regulations 2012 before you proceed

By clicking this button, I confirm that I have read & accepted all the rules & regulations therein.

Click in radio button

After user clicks on a radio button, the user should upload file.

- Copy of Attestation for CAB Application -> User must click at button






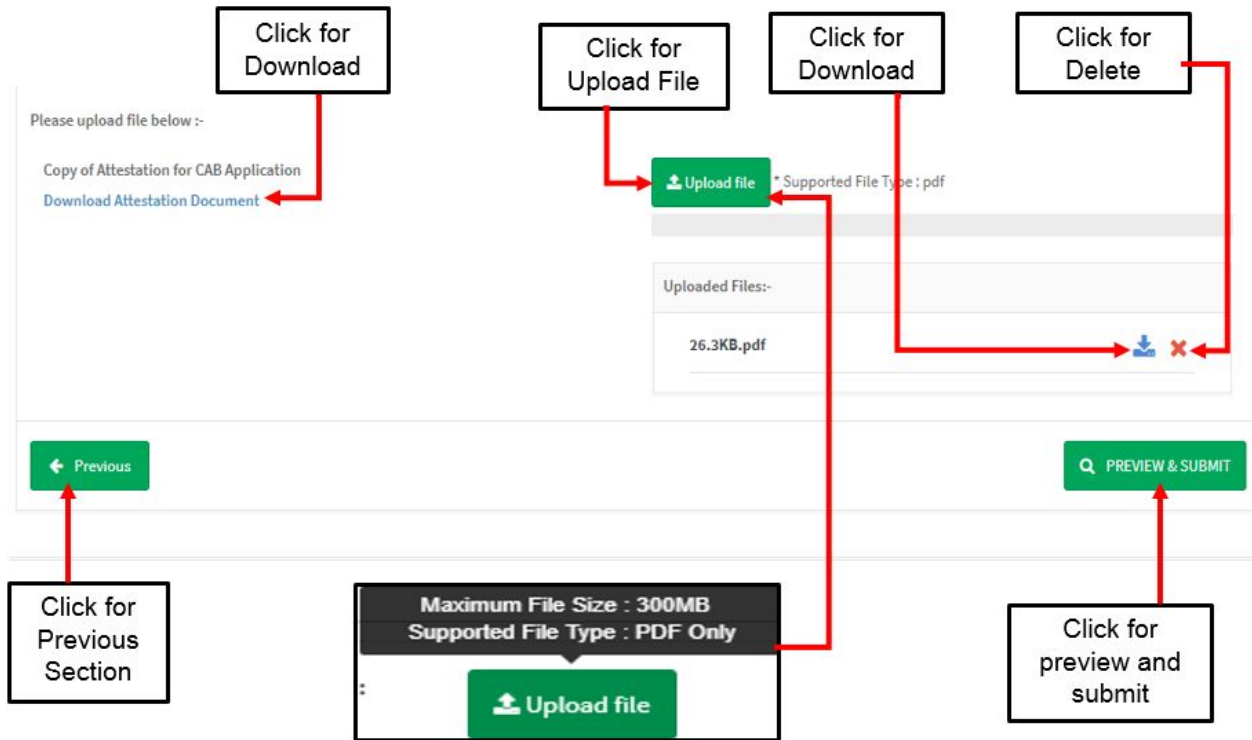
untuk upload file PDF only and not more than 300MB for file size.

User can download the example form which is user click the link "[Download Attestation Document](#)" and example form will be automatically download



.User also can preview the file which is user click the link file name and the file will appear. Besides that, user can

download and print by clicking symbol . The user can download and delete the file with click at  for download and  for delete that shown in the figure below.



The user can go back to previous section 4.0 REQUIREMENTS ON QUALITY



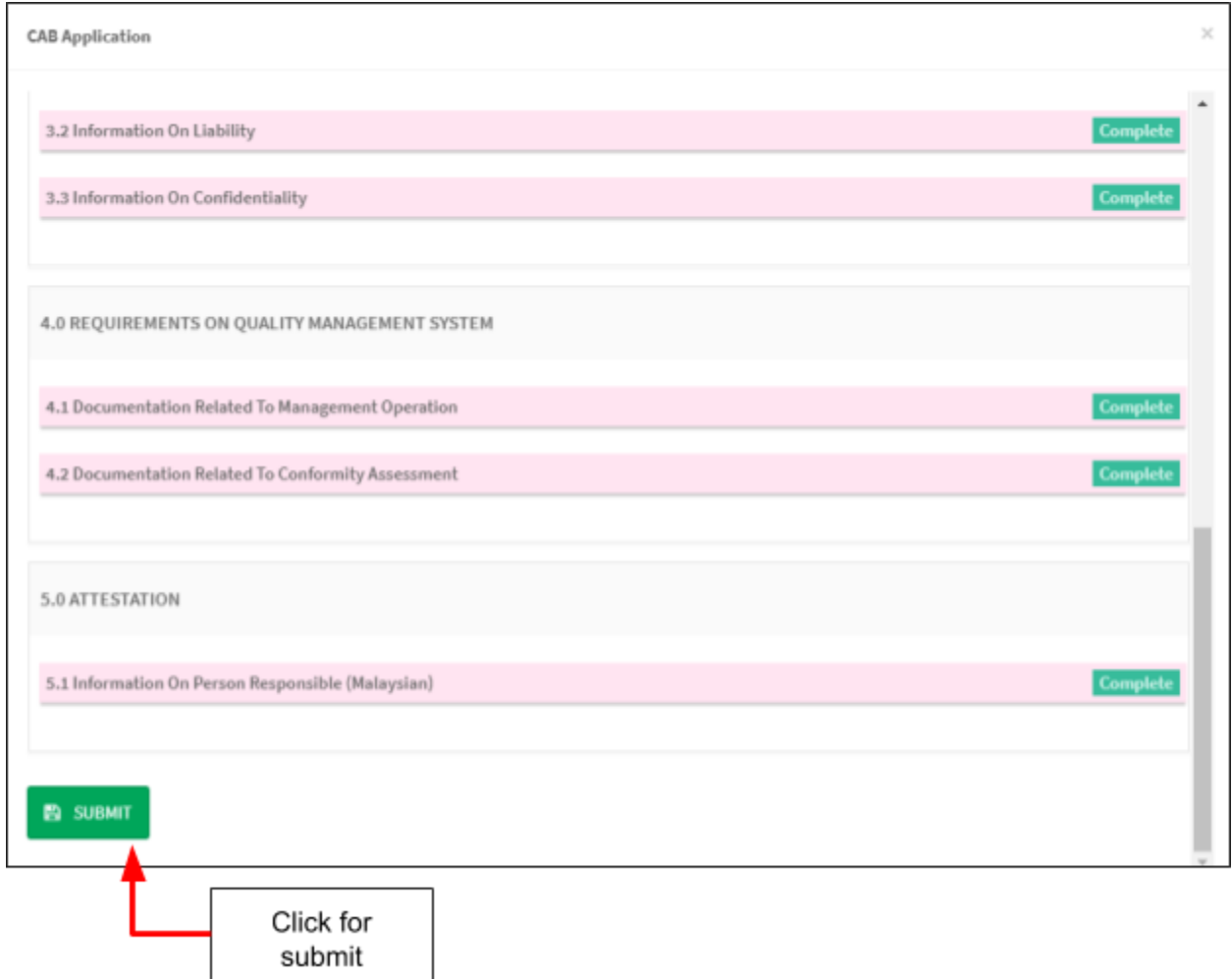
MANAGEMENT SYSTEM which is click the button  that shown in

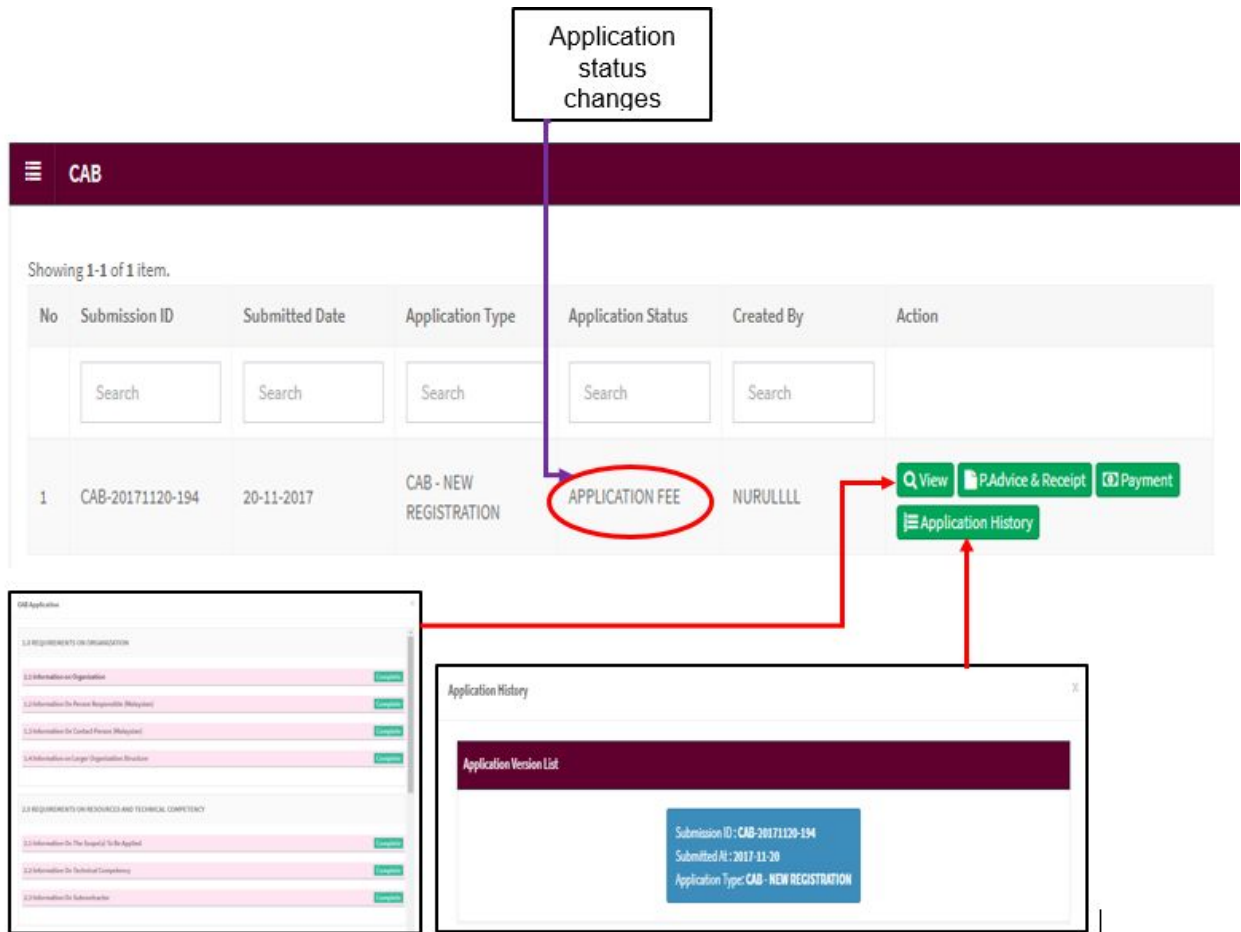
figure above. The user should click at button  to view details of form application and click button “submit” that shown in figure below.





After that, the message will be displayed which is




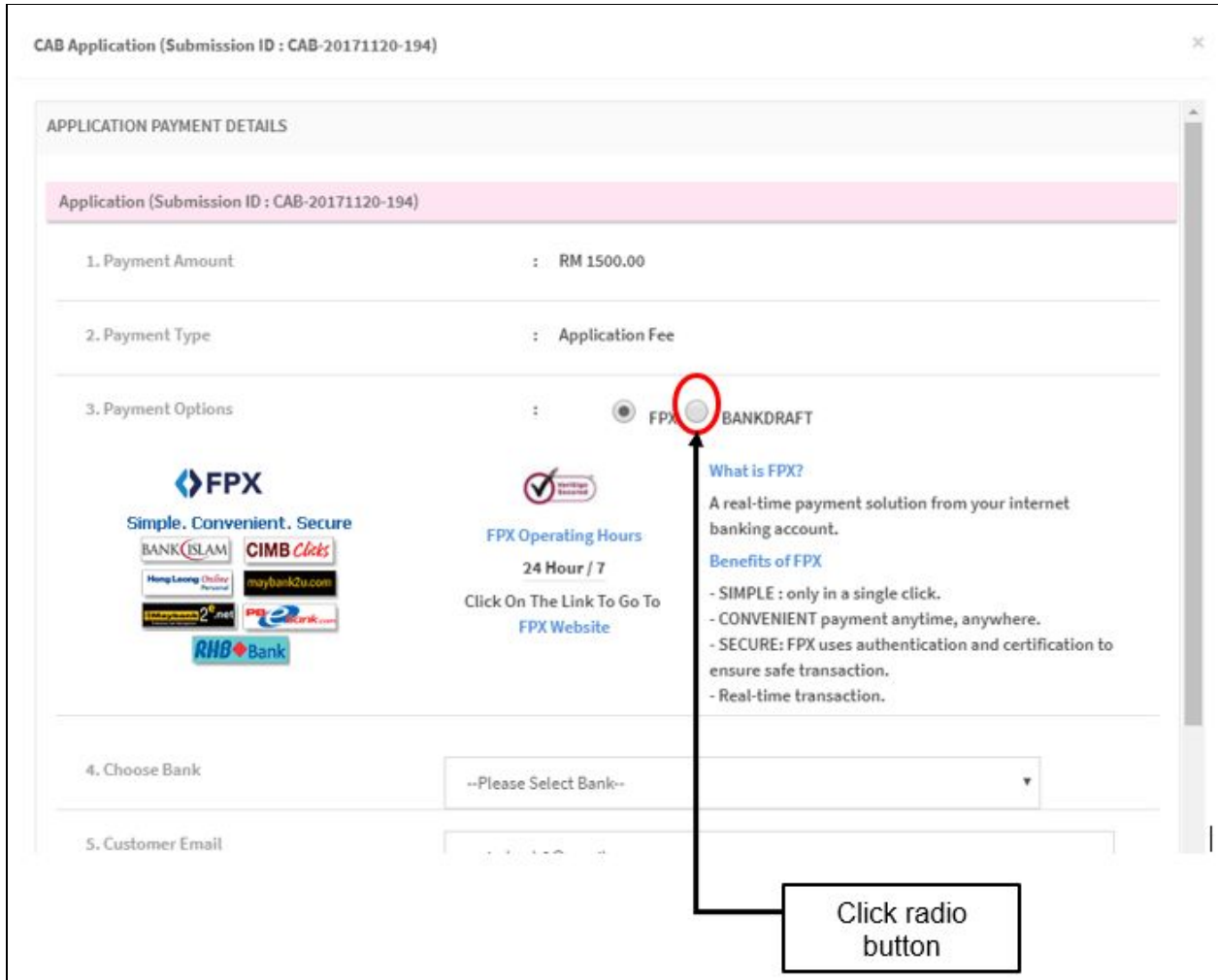
. The application status will be changes to "Application Fee"



The user can click button  to see the application detail. Besides that, user can click  to see the history application.

- **Application fee**

The user should click button  to make the payment in Bank draft or FPX. the figure below show the payment Bank draft process. User should click radio button at Bank Draft that shown in the figure below.



The page for payment will be displayed.

The user should click on button “Add Bankdraft” to display the form of bank draft which is Bankdraft no., amount and upload file.

CAB Application (Submission ID : CAB-20171120-194)

Application (Submission ID : CAB-20171120-194)

1. Payment Amount : RM 1500.00

2. Payment Type : Application Fee

3. Payment Options : FPX BANKDRAFT

1. Bayaran boleh dibuat dengan menggunakan Bank Deraf atas nama "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Sila cetak dan bawa invois ini bersama Bank Deraf ke alamat seperti yang tertera di atas; atau
 Payment shall be made through Bank Draft to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Please print and bring this invoice together with the Bank Draft to our address shown above; or

2. Bayaran atas talian boleh dibuat melalui laman sesawang www.mda.gov.my dan mengikut arahan yang diberikan.
 Online payment shall be made through www.mda.gov.my and follow the instructions given.

3. Bayaran hendaklah dibuat dalam tempoh 30 hari dari tarikh invois ini.
 Payment must be made within 30 days of the date shown on this invoice.

4. Bankdraft(s) Details

[+ Add Bankdraft](#)

**Insufficient Amount!*

No	Bankdraft Number	Bankdraft Amount	Bankdraft FileName	Action

Bank Draf No. *

Amount *

[Upload File](#)

[Add](#)

Click for Upload file

Click for add Bank draft

After bank draft fill all form, the user should click on "Add" to proceed. The details of Bank draft will be displayed that shown in the figure below.

No	Bankdraft Number	Bankdraft Amount	Bankdraft FileName	Action
1	7677	1500.00	26.3KB.pdf	Delete

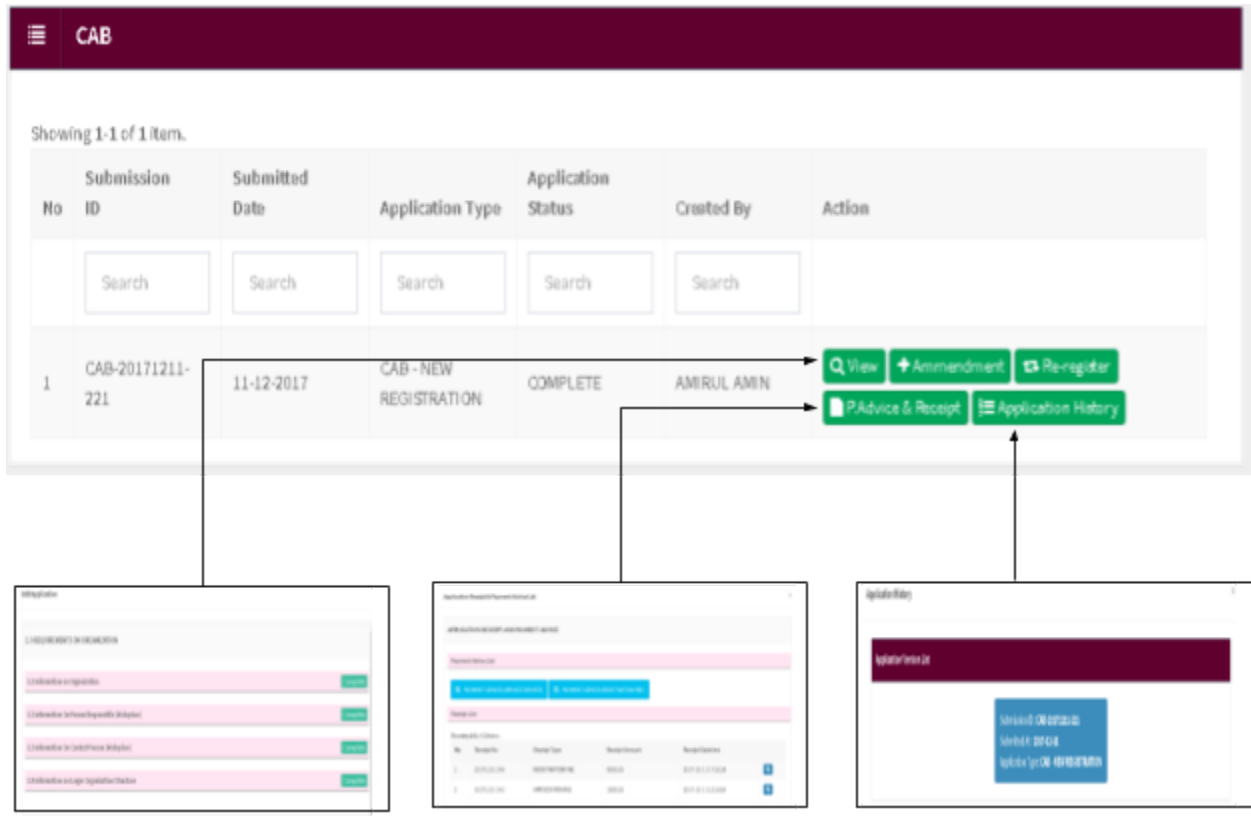
Click for preview and download file

Click for delete


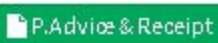

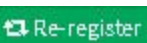

The user can click the file name to view the file and download the file. If user want to delete bankdraft, user should click button [Delete](#) to delete bank draft.

Lastly, user click button  to save bankdraft.


3.0 APPLICATION COMPLETE

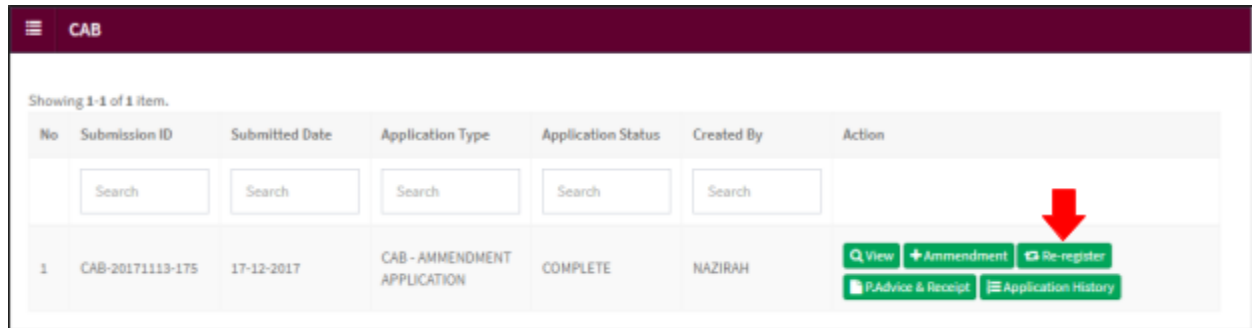


The screenshot displays the CAB application interface. At the top, there is a header with a menu icon and the text 'CAB'. Below the header, it says 'Showing 1-1 of 1 item.' A table with the following columns is shown: 'Submission No', 'Submission ID', 'Submitted Date', 'Application Type', 'Application Status', 'Created By', and 'Action'. The table contains one row with the following data: Submission No: 1, Submission ID: CAB-20171211-221, Submitted Date: 11-12-2017, Application Type: CAB-NEW REGISTRATION, Application Status: COMPLETE, and Created By: AMIRUL AMIN. Below the table, there are five action buttons: 'View', '+ Amendment', 'Re-register', 'PAdvice & Receipt', and 'Application History'. Three inset images are shown below the table, each connected to a button by a line. The first inset image is connected to the 'View' button and shows a form with several input fields and a 'View' button. The second inset image is connected to the 'PAdvice & Receipt' button and shows a receipt form with a table of items. The third inset image is connected to the 'Application History' button and shows a list of application history items.

- Click on the  button to view the application details.
- Click on the  button to view the receipt.
- Click on the  button to view the application history.
- Click on the  button to re register the application process.
- Click on the  button to Amendment the application.

3.1 RE-REGISTER

User click  button to re-register CAB application.



Showing 1-1 of 1 item.

No	Submission ID	Submitted Date	Application Type	Application Status	Created By	Action
	<input type="text" value="Search"/>	<input type="text" value="Search"/>	<input type="text" value="Search"/>	<input type="text" value="Search"/>	<input type="text" value="Search"/>	
1	CAB-20171113-175	17-12-2017	CAB - AMMENDMENT APPLICATION	COMPLETE	NAZIRAH	View + Amendment Re-register P.Advice & Receipt Application History

Next, user will go to 1.0 REQUIREMENT OF ORGANIZATION page. User have to

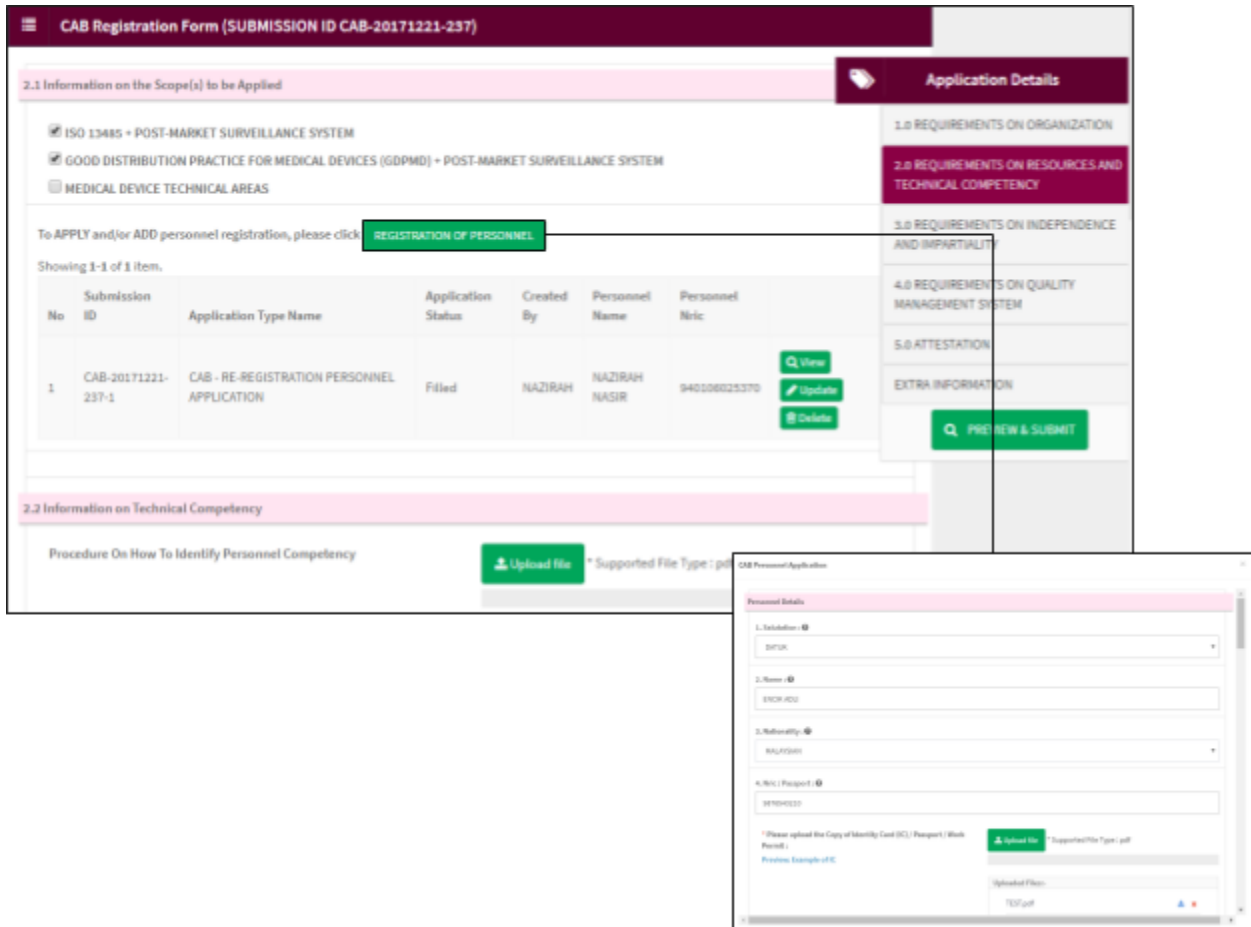
complete all fields with (*). User click






to go to the next step.

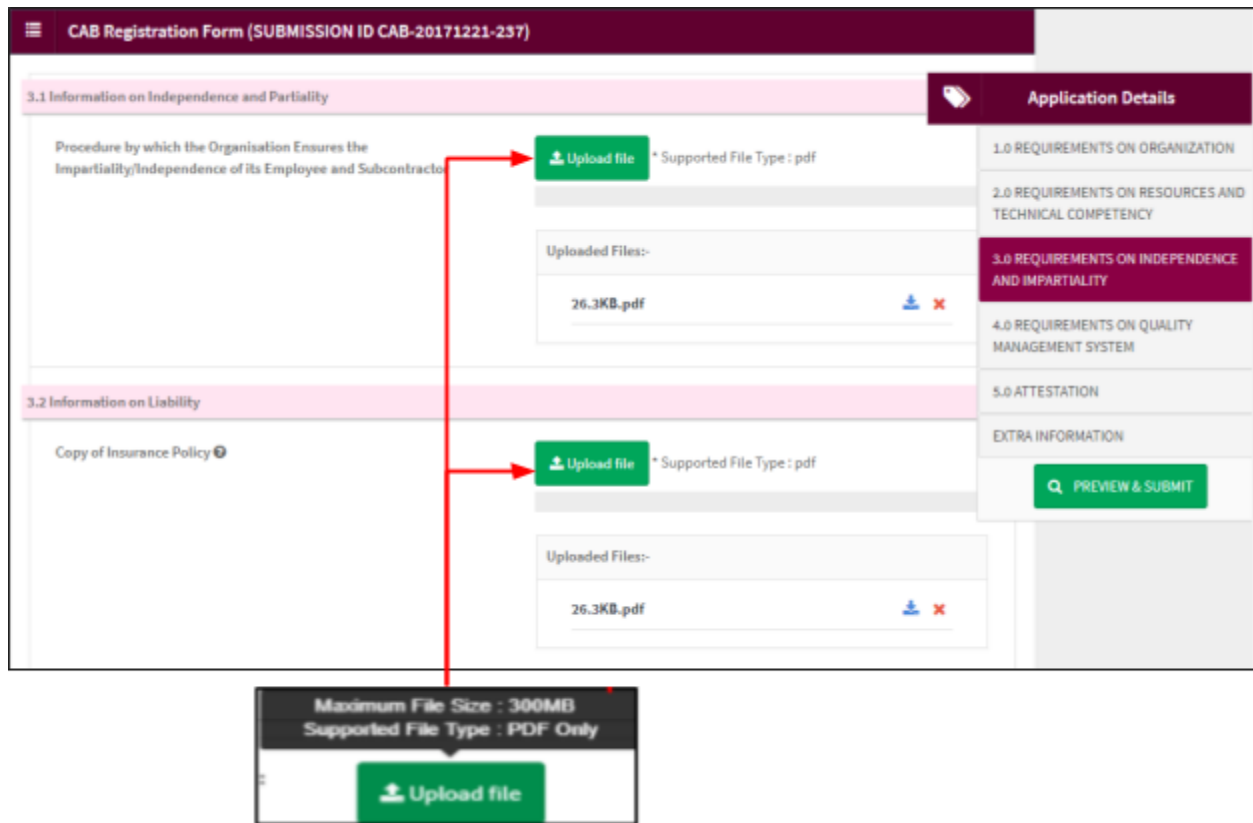
The screenshot displays the 'CAB Registration Form' interface. The top header shows the submission ID 'CAB-20171221-237'. The main content area is divided into two sections: '1.1 Information on Organization' and 'Application Details'. The '1.1 Information on Organization' section contains several input fields: '1. Organization Name' (filled with 'NAZIRAH'), '2. Organization Details' (with a sub-section 'Address Of Organization' containing 'batu 7 jalan sanglang' and 'eg: Ampang'), 'State' (dropdown menu with 'KEDAH' selected), 'City' (filled with 'ALOR SETAR'), and 'Postcode' (filled with '06150'). The 'Application Details' sidebar on the right lists requirements: '1.0 REQUIREMENTS ON ORGANIZATION' (highlighted in dark red), '2.0 REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY', '3.0 REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY', '4.0 REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM', '5.0 ATTESTATION', and 'EXTRA INFORMATION'. At the bottom of the sidebar is a green 'PREVIEW & SUBMIT' button.




The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. User have to complete all fields with (*).



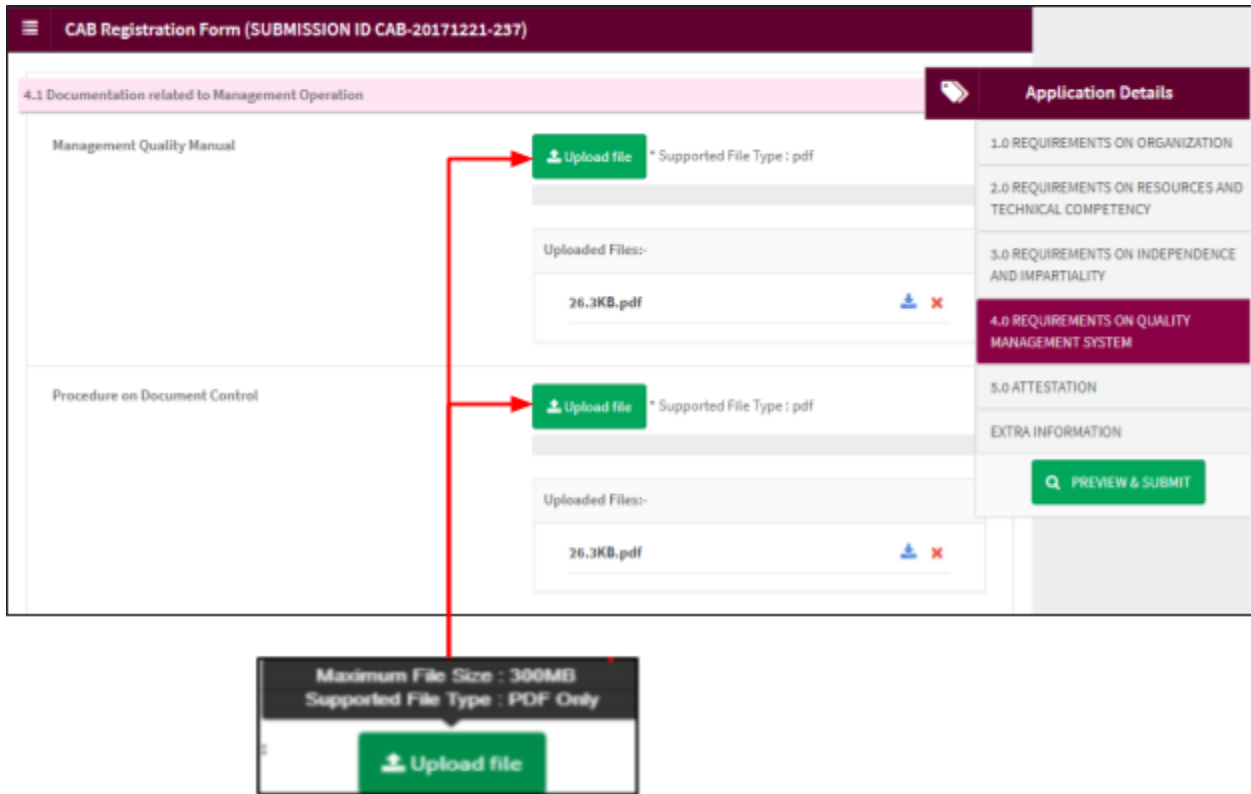
Click  to upload. **The file must be pdf format and size not more than 300 MB.** User click  to go to the next step. User click  to go to the previous form.

The diagram below show 3.0 REQUIREMENT ON INDEPENDENCE AND IMPARTIALITY form. User have to complete this fields.

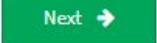



Click  to upload. **The file must be pdf format and size not more than 300 MB.** User click  to go to the next step. User click  to go to the previous form.




The diagram below show 4.0 REQUIREMENT ON QUALITY MANAGEMENT SYSTEM form. User have to complete in this fields.



Click  to upload. **The file must be pdf format and size not more than**

300 MB. User click  to go to the next step. User click  to go to the previous

The diagram below show 5.0 ATTESTATION form. User have to complete these fields.

Click  to upload. **The file must be pdf format and size not more than 300 MB.** User click  to go to the next step. User click  to submit application.

The diagram below show EXTRA INFORMATION form. This page will display

information file uploaded by user. User click



to submit application.

CAB Registration Form (SUBMISSION ID CAB-20171221-237)

Extra Information And File Upload

Application Details

Extra Information Files & Remarks

Showing 1-5 of 15 items.

- HJKGKJ
26.3KB.pdf
13-11-2017 (10:21 pm)
- JKGHJGJ
26.3KB.pdf
13-11-2017 (10:20 pm)
- JBNMVNM
26.3KB.pdf
13-11-2017 (10:14 pm)
- HGVB
26.3KB.pdf
13-11-2017 (10:18 pm)
- FDGFDG
26.3KB.pdf
13-11-2017 (7:57 pm)

1.0 REQUIREMENTS ON ORGANIZATION

2.0 REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY

3.0 REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY

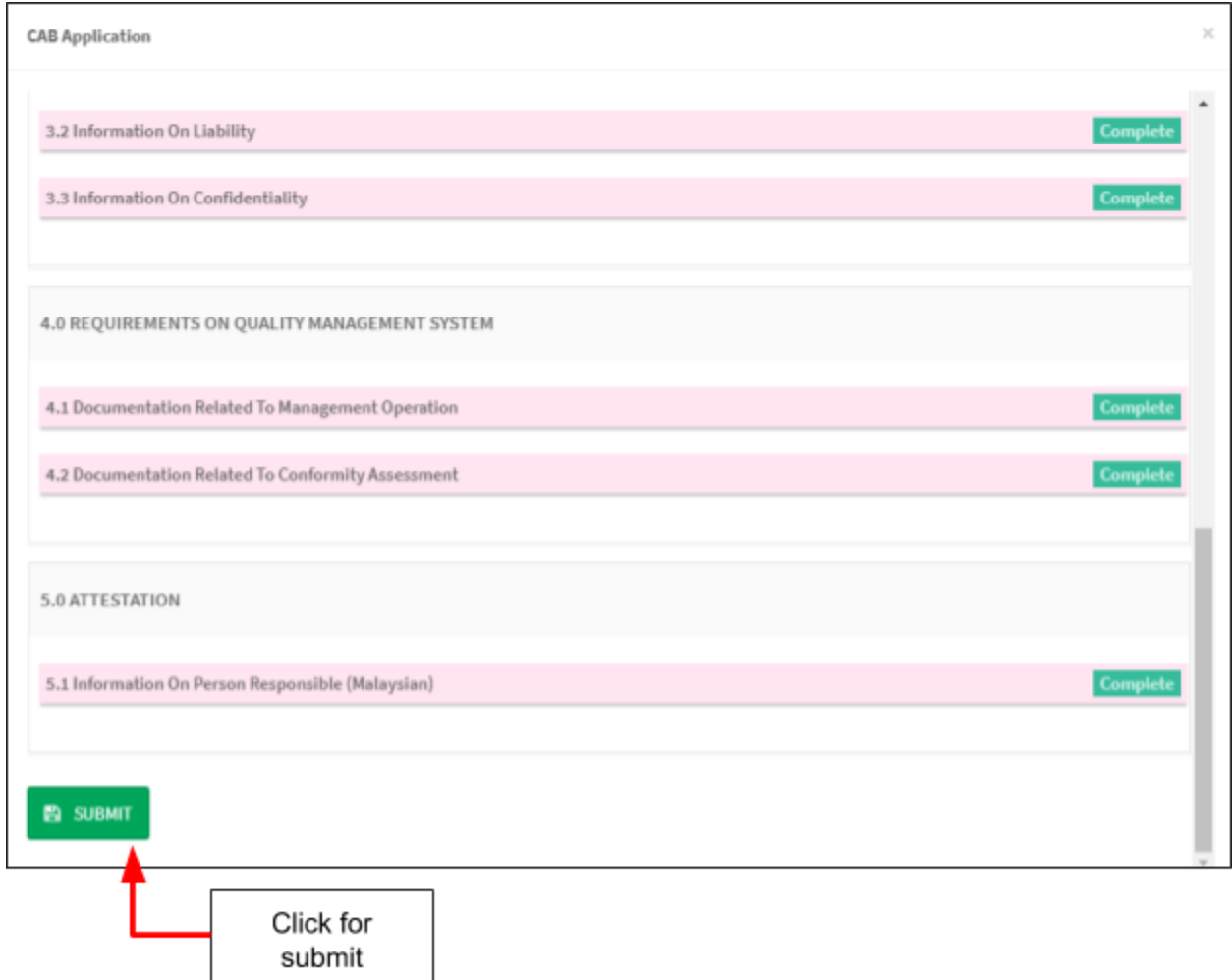
4.0 REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM

5.0 ATTESTATION

EXTRA INFORMATION

PREVIEW & SUBMIT

first < 1 2 > last



After that, the message will be displayed which is



. The application status will be changed to "Application Fee"

3.2 AMENDMENT

No	Submission ID	Submitted Date	Application Type	Application Status	Created By	Action
1	CAB-20171213-235	14-12-2017	CAB - AMMENDMENT APPLICATION	COMPLETE	AMIRUL AMIN	View + Amendment Re-register P-Advise & Receipt Application History

Click on the [+ Amendment](#) button to amend the application.

User will go to 1.0 REQUIREMENT ON ORGANIZATION page. In this form user make changes at :

CAB Registration Form (SUBMISSION ID CAB-20171213-235)

1.1 Information on Organization

1. Organization Name :

2. Organization Details

Address Of Organization :

State :

City :

- 1.1 Information on Organization
- 1.2 Information On Person Responsible (Malaysian)
- 1.3 Information On Contact Person (Malaysian)
- 1.4 Information on Larger Organization Structure

Next, user will go to 2.0 REQUIREMENT ON RESOURCE AND TECHNICAL COMPETENCY page. In this form user make changes at :

2.1 Information on the Scope(s) to be Applied

ISO 13485 + POST-MARKET SURVEILLANCE SYSTEM
 GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD) + POST-MARKET SURVEILLANCE SYSTEM
 MEDICAL DEVICE TECHNICAL AREAS

To APPLY and/or ADD personnel registration, please click **REGISTRATION OF PERSONNEL**

Showing 1-1 of 1 item.

No	Submission ID	Application Type Name	Application Status	Created By	Personnel Name	Personnel Nric	
1	CAB-20171213-235-1	CAB - AMMENDMENT PERSONNEL APPLICATION	Filled	AMIRUL AMIN	SYAKIRIN BIN AHMAD	870706344123	View Update

List of Personnel Application !! Click button **+** on the personnel to make ammendment

Showing 1-2 of 2 items.

No	Submission ID	Application Type Name	Application Status Name	Created By	Personnel Name	Personnel Nric	
1	CAB-20171213-235-1	CAB - AMMENDMENT PERSONNEL APPLICATION	REJECT	AMIRUL AMIN	SYAKIRIN BIN AHMAD	870706344123	View Amendment

2.1 Information on the Scope(s) to be Applied

2.2 Information on Technical Competency

2.3 Information on Subcontractor

Next, user will go to 3.0 REQUIREMENT ON INDEPENDENCE AND IMPARTIALITY page. In this form user make changes at :

3.1 Information on Independence and Partiality

Procedure by which the Organisation Ensures the Impartiality/Independence of its Employee and Subcontractor

Upload file * Supported File Type : pdf

Uploaded Files:-

Nur SyakirinAmirruddin-KL_TNW2053_SEC03_051-Letter.pdf

3.2 Information on Liability

Copy of Insurance Policy

Upload file * Supported File Type : pdf

Uploaded Files:-

Nur SyakirinAmirruddin-KL_TNW2053_SEC03_051-Letter.pdf

3.1 Information on Independence and Partiality

3.2 Information on Liability

3.3 Information on Confidentiality

Next, user will go to 4.0 REQUIREMENT ON QUALITY MANAGEMENT SYSTEM page.

In this form user make changes at :

The screenshot displays the 'CAB Registration Form (SUBMISSION ID CAB-20171213-235)'. It features two main sections for document uploads:

- 4.1 Documentation related to Management Operation**: This section includes a sub-section for 'Management Quality Manual'. It contains an 'Upload file' button (with a note '* Supported File Type : pdf') and a list of uploaded files. One file is listed: 'Nur SyakirinAmirruddin-KL_TNW2053_SEC03_051-Letter.pdf', which includes a download icon and a delete icon.
- Procedure on Document Control**: This section also includes an 'Upload file' button (with a note '* Supported File Type : pdf') and a list of uploaded files. One file is listed: 'Nur SyakirinAmirruddin-KL_TNW2053_SEC03_051-Letter.pdf', which includes a download icon and a delete icon.

4.1 Documentation related to Management Operation

4.2 Documentation related to Conformity Assessment

Next, user will go to 5.0 ATTESTATION page. In this form user make changes at :

Person Responsible Identity Card Number :
 970706385187

hereby attest that the information provided on this application and any attached documents or certificates which had been duly certified true copy are accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

IMPORTANT: Please read the Medical Device Act 2012 (Act 737) & Medical Device Regulations 2012 before you proceed

By clicking this button, I confirm that I have read & accepted all the rules & regulations therein.

Please upload file below :-

Copy of Attestation for CAB Application
[Download Attestation Document](#)

[Upload file](#) * Supported File Type : pdf

Uploaded Files:-
 Nur SyakirinAmirruddin-KL_TNW2053_SEC03_051-Letter.pdf

[Previous](#) [PREVIEW & SUBMIT](#)

5.1 Attestation by Person Responsible

After user finish change the content in the application click on the

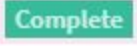



button to submit the application.

CAB Application

[SUBMIT](#) ← Submit the Application

1.0 REQUIREMENTS ON ORGANIZATION	Status
1.1 Information on Organization	Complete
1.2 Information On Person Responsible (Malaysian)	Complete
1.3 Information On Contact Person (Malaysian)	Complete
1.4 Information on Larger Organization Structure	Complete

Submission only can do if all form status is . If not, user need to complete the form. Click  to submit application or at the bottom of the application that is also 'Submit' button.

Amendment will go through backend user :

- I. Evaluation
- II. Cabac Meeting
 - A. Audit Unit (Optional)
 - B. Interview(Optional)
 - C. Audit and Interview(Optional)
- III. Print Certificate