Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201929

19 OCT 2020

TO : **ALL RRD STAKEHOLDERS AND THE GENERAL PUBLIC**

SUBJECT : **Online Cascading and Pilot Implementation of the FDA RRD Portal for the Issuance of License to Operate (LTO) and Certificate of Facility Registration (CFR) of Radiation Facilities**

The Food and Drug Administration through Center for Device Regulation, Radiation Health and Research sought to re-engineer and streamline its authorization processes to establish a more efficient way in government service delivery. As part of these efforts, the FDA through Department of Health (DOH) Administrative Order (AO) No. 2020-0035 or the "*Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorization*" adopted a new online authorization process for radiation facilities under its jurisdiction through the FDA RRD Portal.

The FDA invites radiation facilities to participate in the online cascading and pilot implementation of the RRD Portal for the issuance of License to Operate (LTO) and Certificate of Facility Registration (CFR) for Radiation Facilities.

Online Cascading	October 28, 2020
Participants	**Only 300 participants** on a first come first served basis via Zoom will be accommodated. Strictly one (1) participant per company/facility. You may register, through this link https://forms.gle/NdWvigqdZ7N2hJNU9
PILOT IMPLEMENTATION OF FDA RRD PORTAL	
Target Participants/ Start of Pilot Implementation	National Capital Region - **November 9, 2020** Nationwide - **December 9, 2020**
Type of Application	Initial and Renewal Application of License to Operate (LTO) and Certificate of Facility Registration (CFR) for Radiation Facilities
Fees to be Paid	Based on the Current Schedule of Fees and Charges (AO No. 29 s. 2000, FDA Circular No. 2011-003, 2011-004)
Requirements	In accordance with Annex **C** and **D** of AO 2020-0035
Validity of Authorization	In accordance with Section VI of AO 2020-0035 Initial LTO and CFR authorizations shall have **three (3) years validity** Renewal LTO and CFR authorizations shall have **five (5) years validity**

All processes shall be done in accordance to the general and specific guidelines of DOH AO No. 2020-0035.

The detailed step-by-step procedure shall follow the illustrative guide shown in Annex A-C of this Advisory.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Annex A
Procedure for the Use of RRD Portal for User Account Registration

Login Screen

Figure 1. *RRD Portal Login Page.*

STEP 1: Go to https://rrdportal.fda.gov.ph.

STEP 2: Click the "Create User Account" button found below the login credential fields.

REQUEST/APPLICATION PAGE

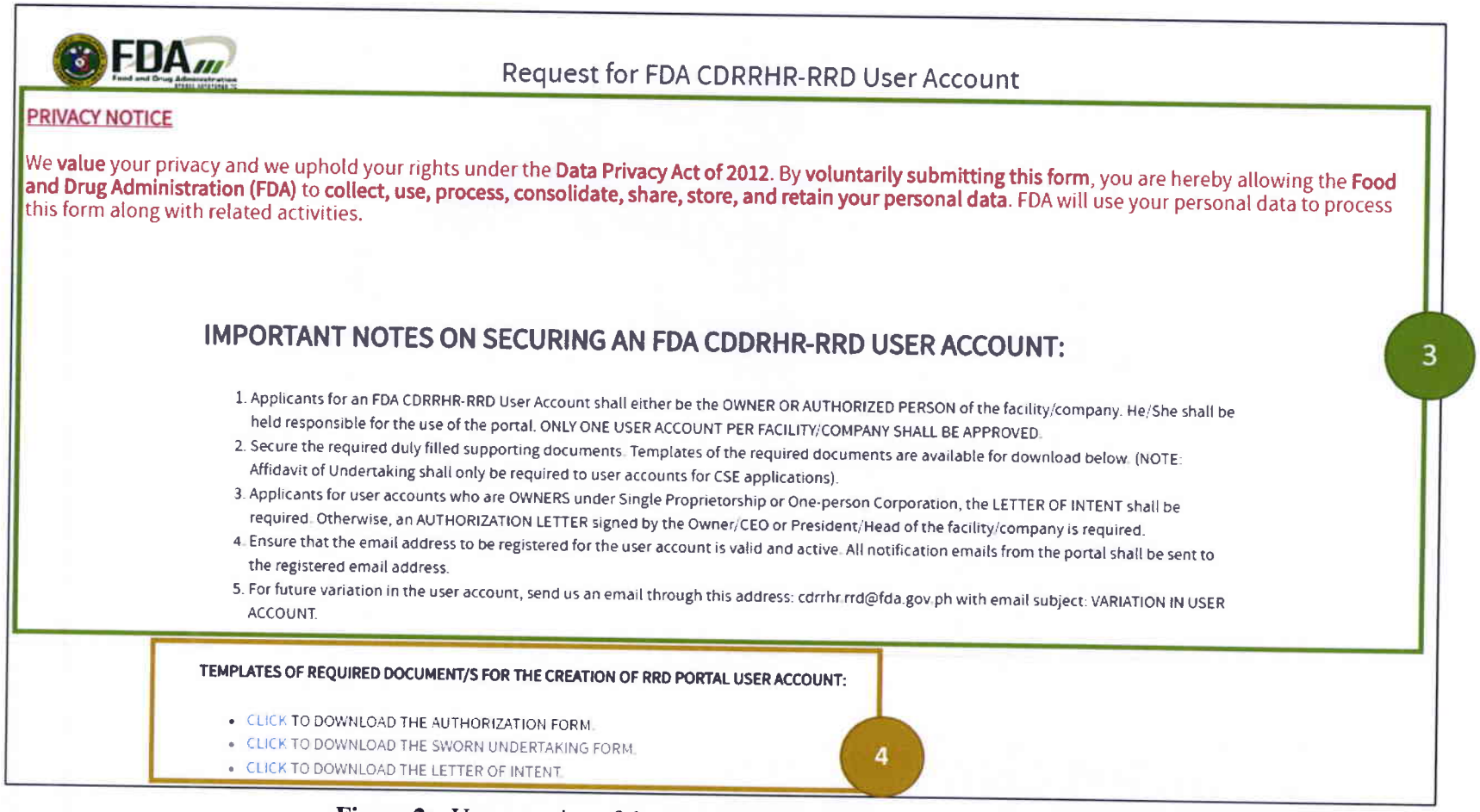


Figure 2a. Upper section of the FDA CDRRHR-RRD user account registration page

STEP 3: Ensure that the Privacy Notice and important notes on securing a user account are read and understood.

STEP 4: All templates of the required document/s can be found and downloaded on this section of the page. The applicants shall download and use the respective template/s when requesting an FDA CDRRHR-RRD User Account. These are to be duly filled and notarized.

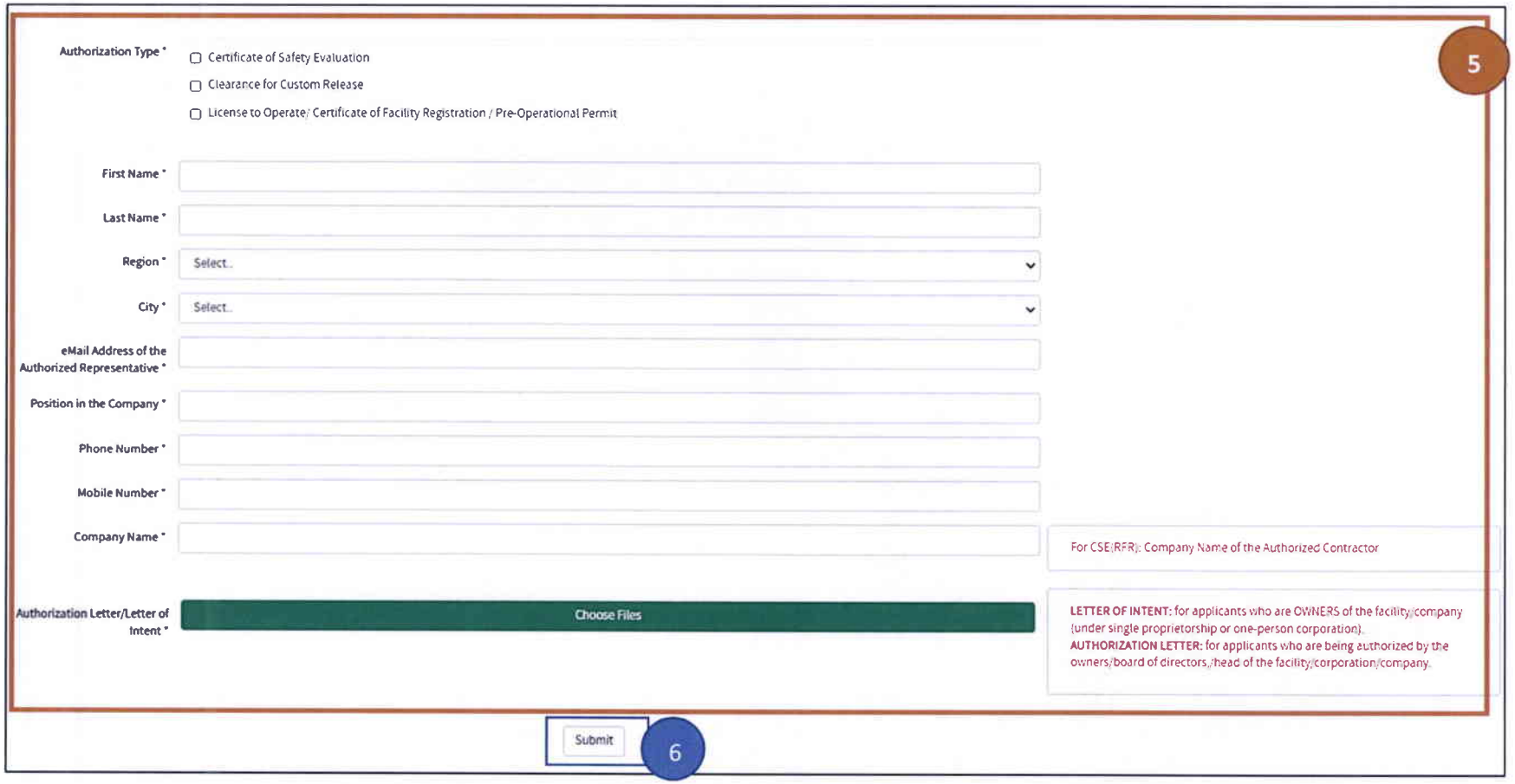


Figure 2b. Lower section of the FDA CDRRHR-RRD user account registration

STEP 5: Select the type of authorization and fill in the correct information in all the required fields. Depending on the authorization type, upload the required document/s for the creation of the user account.

STEP 6: Review all provided information. To officially submit the request for a RRD Portal User Account, click the "Submit" button.

CONFIRMATION PAGE

THANK YOU!!

Your RRDPortal account has been submitted and subject for approval!!

You will receive an email within 24 to 48 hours upon verification of your account.

Click here to go back to rrdportal to proceed

Annex B

Procedure for the Use of RRD Portal for License to Operate (LTO) Application

Login Screen

Figure 1. *RRD Portal Login Page.*

STEP 1: Log in to RRD PORTAL: https://rrdportal.fda.gov.ph using the credentials sent to the email address used for the creation of user account.

Home Page

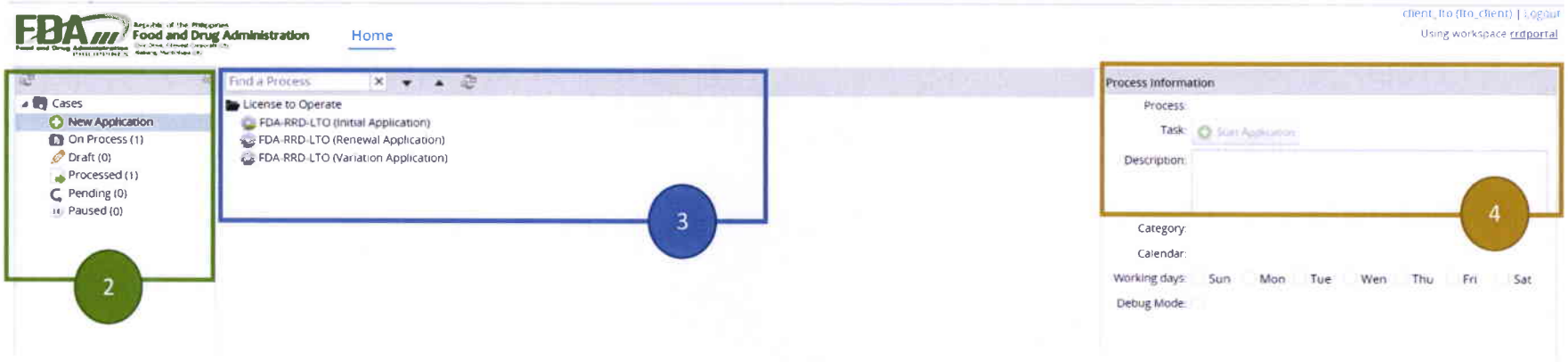


Figure 2. *RRDPortal Home Tab.*

STEP 2: To start an application click "New Application" located in the left pane of the page.

STEP 3: Select "FDA-RRD-LTO (Initial Application)" under the "License to Operate" Menu located at the center pane of the page.

STEP 4: Click the "Start Application" button located at the right pane of the page to initiate the application.

Terms And Conditions Page

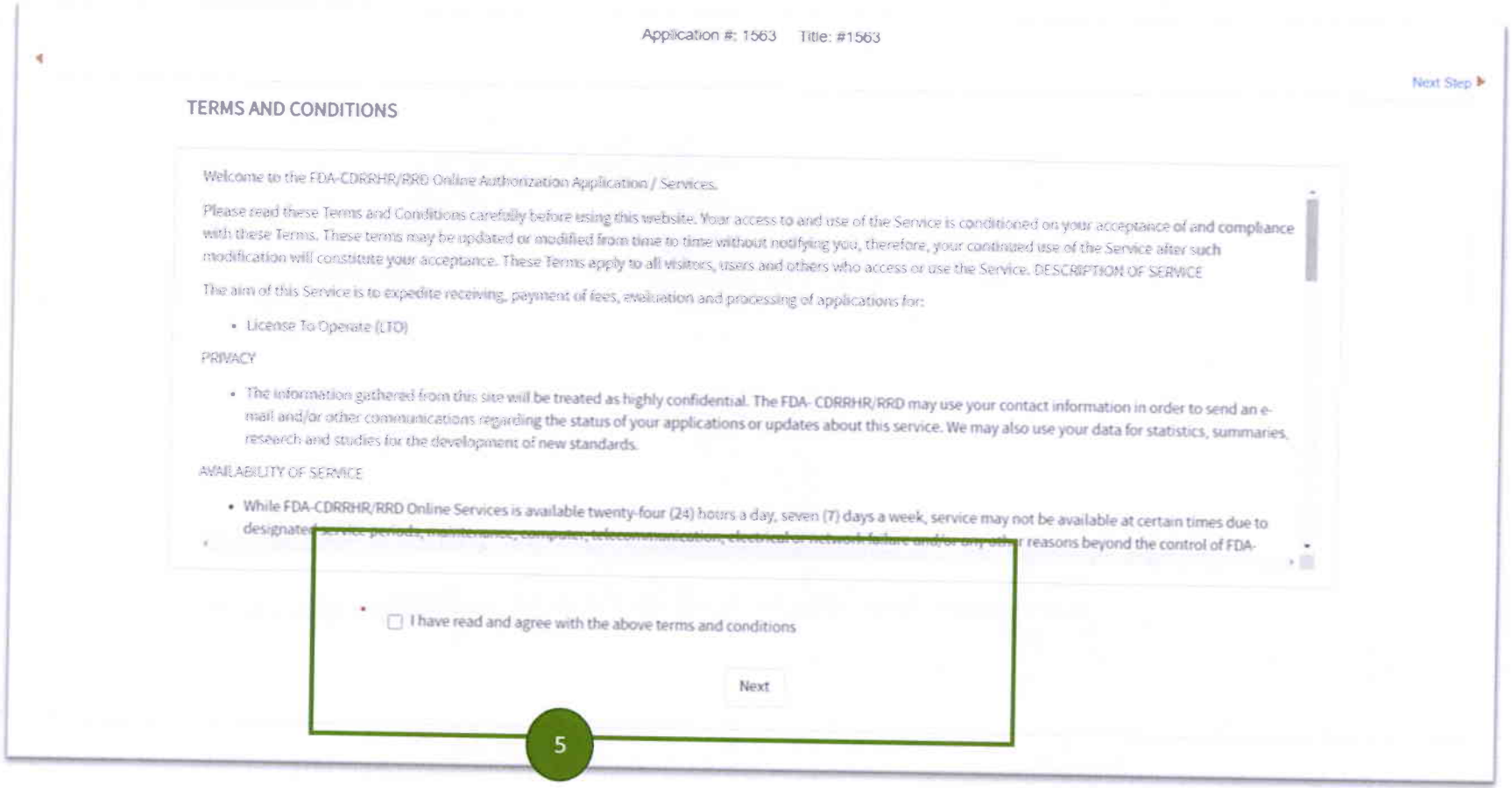
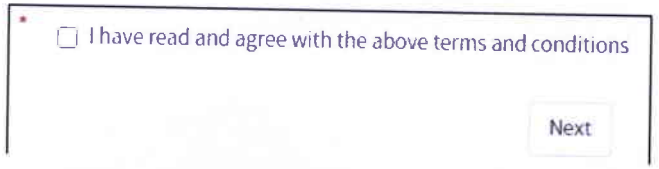


Figure 3. *RRDPortal Terms and Condition.*

STEP 5: Read the Terms and Conditions of using the RRD portal carefully then tick *"I have read and agree with the above terms and conditions"*. Click "Next" to proceed.



General Information Page

GENERAL INFORMATION

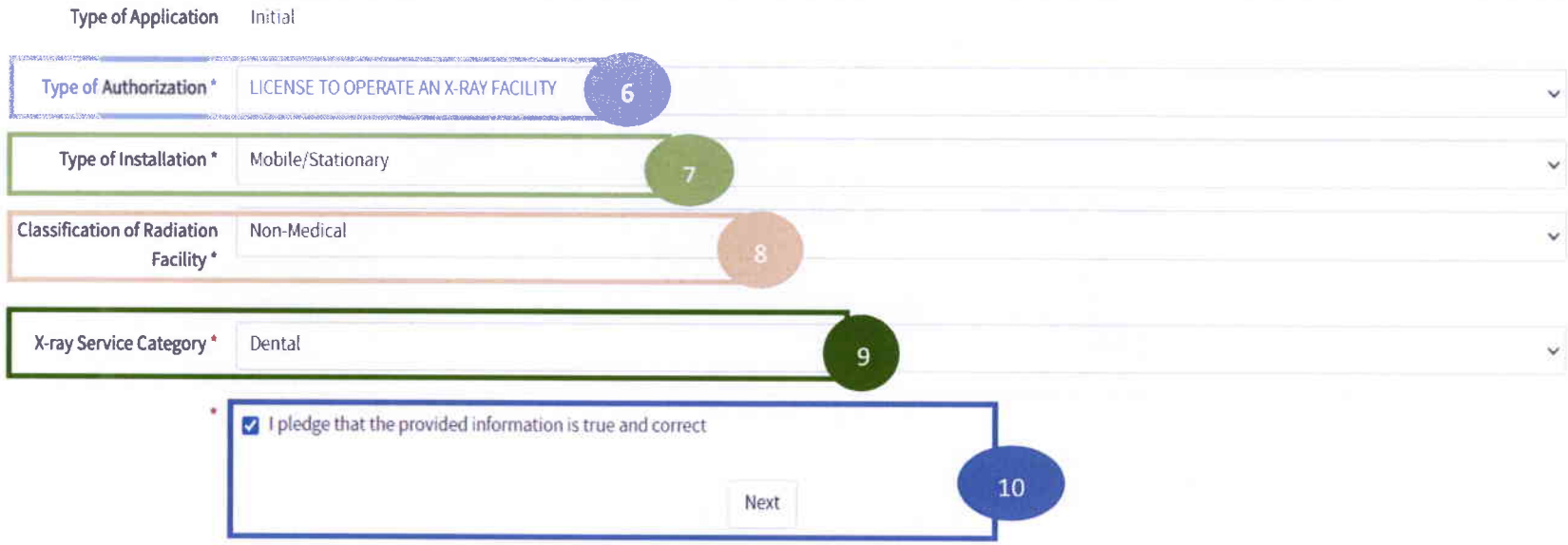
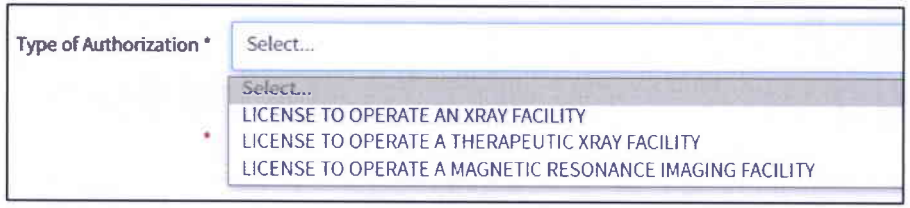


Figure 4. *RRDPortal General Information.*

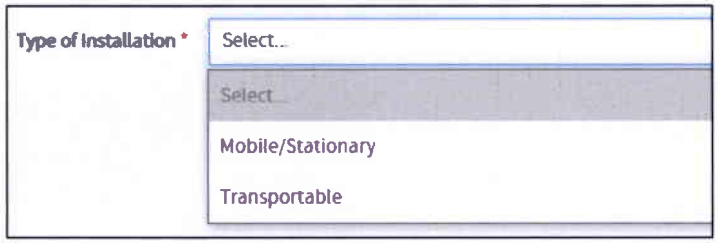
STEP 6: In the "Type of Authorization" drop-down menu, select the type of authorization to be applied.

Options: *"LICENSE TO OPERATE AN X-RAY FACILITY", "LICENSE TO OPERATE A THERAPEUTIC X-RAY FACILITY"* or *"LICENSE TO OPERATE A MAGNETIC RESONANCE IMAGING FACILITY"*

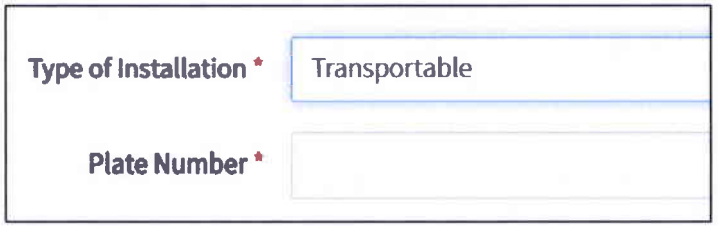


STEP 7: Select the "Type of Installation" of the x-ray machine.

Options: ***"Mobile/Stationary" or "Transportable"***



If ***Transportable*** is selected, indicate the Plate Number of the vehicle

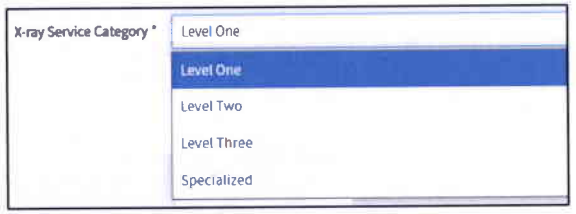


STEP 8: Select the "Classification of Radiation Facility"

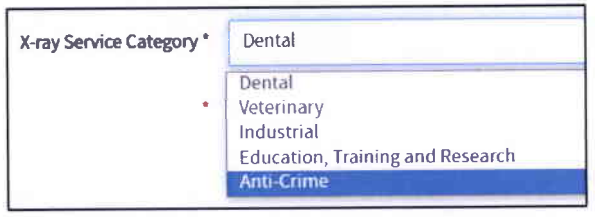
Options: ***"Medical"*** or ***"Non-Medical"***

STEP 9: Select the "X-ray Service Category"

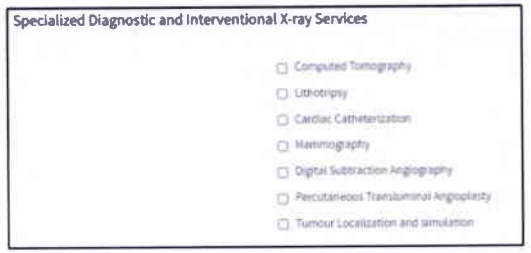
Option 1: If ***"Medical"*** Radiation Facility is selected, specify if ***Level One, Level Two, Level Three,*** **or** ***Specialized***



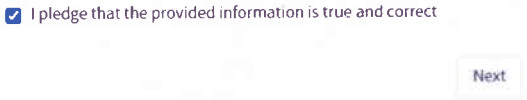
Option 2: If ***"Non-Medical"*** Radiation Facility is selected, specify if ***Dental, Veterinary, Industrial, Anti-Crime, or Educational, Training and Research***



NOTE: Selections for "*Specialized Diagnostic and Interventional X-ray Services"* shall be open but not required for Medical Radiation Facilities with Level One, Two, or Three X-ray Services Categories. If ***Specialized*** is selected, at least one Specialized Diagnostic and Interventional X-ray Service shall be specified.



STEP 10: Review the information provided then tick *"I pledge that the provided information is true and correct"*. Click "Next" to proceed.



Establishment Information Page

Figure 5. *RRDPortal Establishment Information.*

STEP 11. Fill in the complete and correct details in all the required fields. Review the details then tick "*I pledge that the provided information is true and correct.*". Click "Next" to proceed.

Facility Address Page

Figure 6. *RRDPortal Facility Address.*

STEP 12: Fill in the complete and correct details in all the required fields.

STEP 13: To assist in determining the GPS coordinates, a Map Tool was integrated into the system. To access the Map Tool, click the "Show Map Tool" button. Zoom in to the preset "Blue Pin" to get a closer image of the location of the establishment. The "Blue Pin" may be adjusted to exactly determine the GPS coordinates. Once the location is determined, click the "Submit" button.

STEP 14: Review the details then tick *"I pledge that the provided information is true and correct."* Click the "Next" button to proceed.

Figure 7. *RRDPortal Map Tool*

Map Page

Figure 8. *RRDPortal Map Tool.*

STEP 15. A map with a closer look at the location of the establishment will be shown for further review and verification. Once satisfied, click the "Next" button to proceed. To make adjustments, click "Previous Step" to return to STEP 13.

List of Personnel Page

Figure 7. RRDPortal List of Personnel.

STEP 16: Fill in the complete and correct information in all the required fields.

STEP 17: Click the "Add" button to officially register the information of the personnel. Ensure that all employed radiation workers of the facility are registered in the system

STEP 18: Review all the details provided tick *"I pledge that I have declared all Authorized and Qualified Personnel associated with our facility and the provided information are true and correct."*

STEP 19: Click the "Next" button to proceed.

Machine Details Page

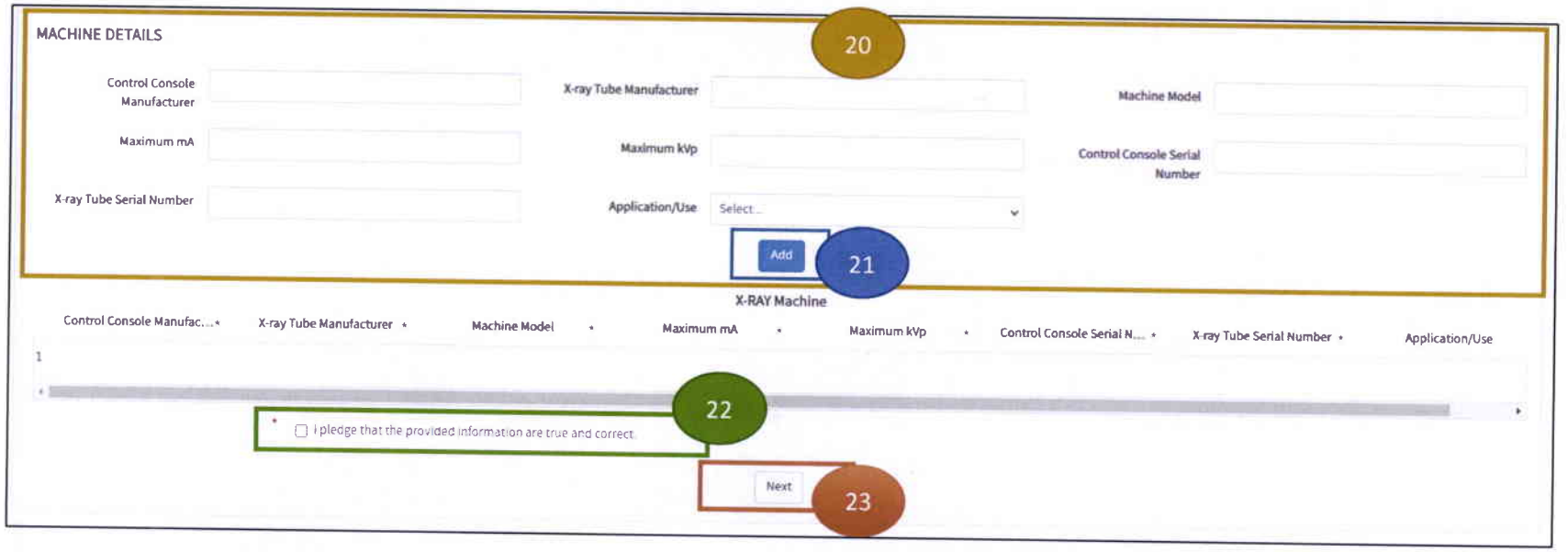


Figure 8. *RRDPortal Machine Details.*

STEP 20: Fill in the complete and correct details in all the required fields.

STEP 21: Click the "Add" button to officially register the details of the x-ray machine. Ensure that all x-ray machines installed or located within the vicinity of the facility are registered in the system.

STEP 22: Review all the details provided then tick *"I pledge that I have declared all x-ray machines installed within and owned by our facility and the provided information are true and correct."*

STEP 23: Click the "Next" button to proceed.

Uploading of Documentary Requirements

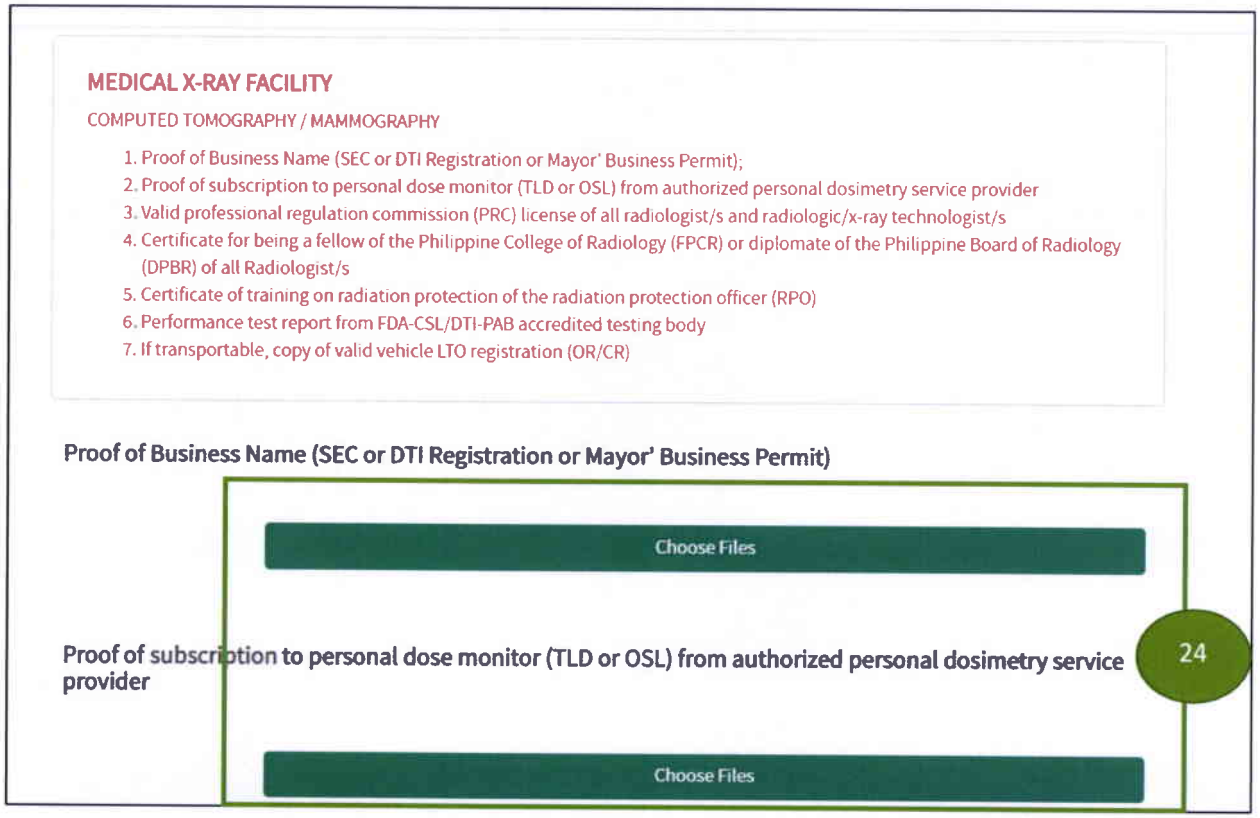


Figure 11a. *The upper portion (center pane) of the RRDPortal Document Requirement Details page.*

STEP 24: To upload the respective documentary requirements, click the "Choose Files" button then locate and select the respective document (in PDF file format) on the computer.

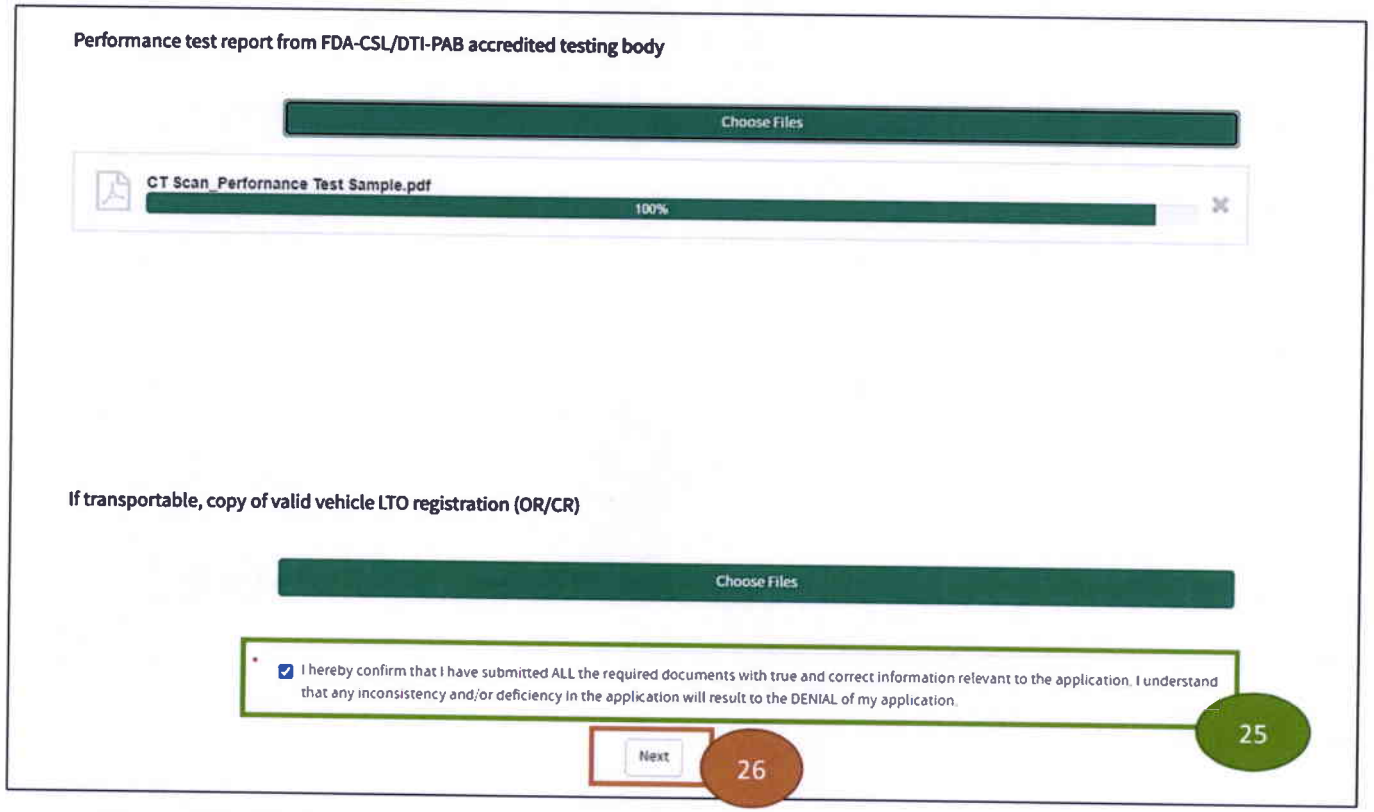


Figure 11b. *The bottom portion (center pane) of the RRDPortal Document Requirement Details page.*

STEP 25: Once all documents have successfully uploaded, ensure and review all provided information then tick *"I hereby confirm that I have submitted ALL the required documents with true and correct information relevant to the application. I understand that any inconsistency and/or deficiency in the application will result in the DENIAL of my application."*

STEP 26: Click "Next" to proceed.

Summary Page

Figure 12a. *The upper portion (center pane) of the RRDPortal Summary Details Page.*

STEP 27: The summary of the application will be shown for the final review. Ensure that all the information and documents provided are complete, true, and correct.

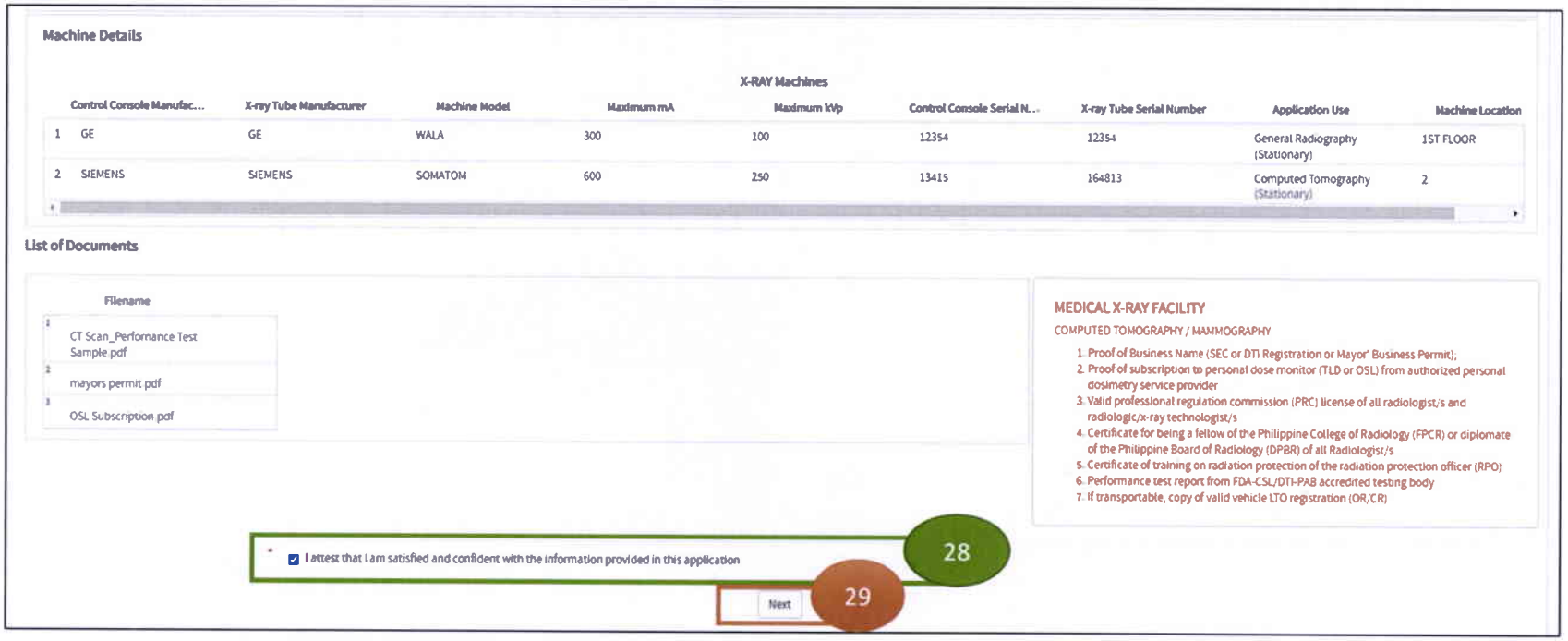
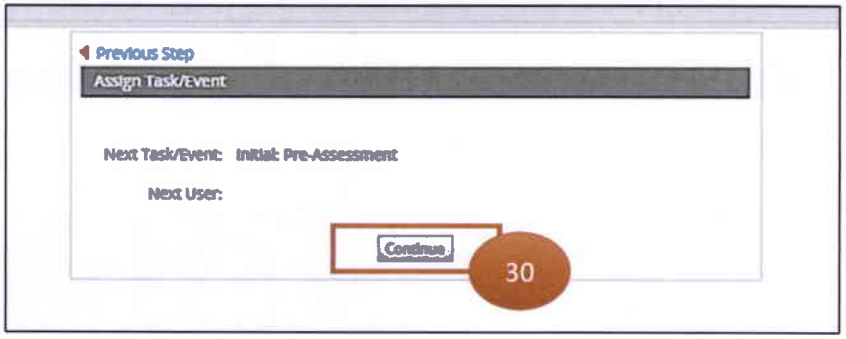


Figure 12b. *The bottom portion (center pane) of the RRDPortal Summary Details Page.*

STEP 28: Once satisfied with the provided information, tick *"I attest that I am satisfied and confident with the information provided in this application."*

STEP 29: Click the "Next" button to submit the application.

END of Application



STEP 30: To officially submit and end the application, click the "Continue" button. The application will be endorsed for pre-assessment and a notification of the result will be sent to the registered email address.

Annex C

Procedure for the Use of RRD Portal for Certificate of Facilty Registration (CFR) Application

Login Screen

Figure 1. *RRD Portal Login Page.*

STEP 1: Log in to RRD PORTAL: https://rrdportal.fda.gov.ph using the credentials sent to the email address used for the creation of user account.

Home Page

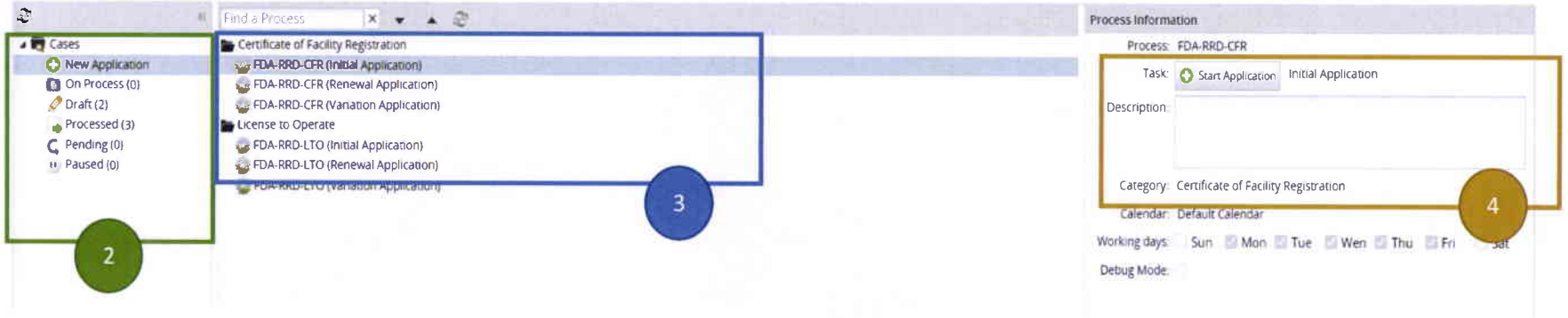


Figure 2. *RRDPortal Home Tab.*

STEP 2: To start an application click "New Application" located in the left pane of the page.

STEP 3: Select "FDA-RRD-CFR (Initial Application)" under the "Certificate of Facility Registration" Menu located at the center pane of the page.

STEP 4: Click the "Start Application" button located at the right pane of the page to initiate the application.

Terms And Conditions Page

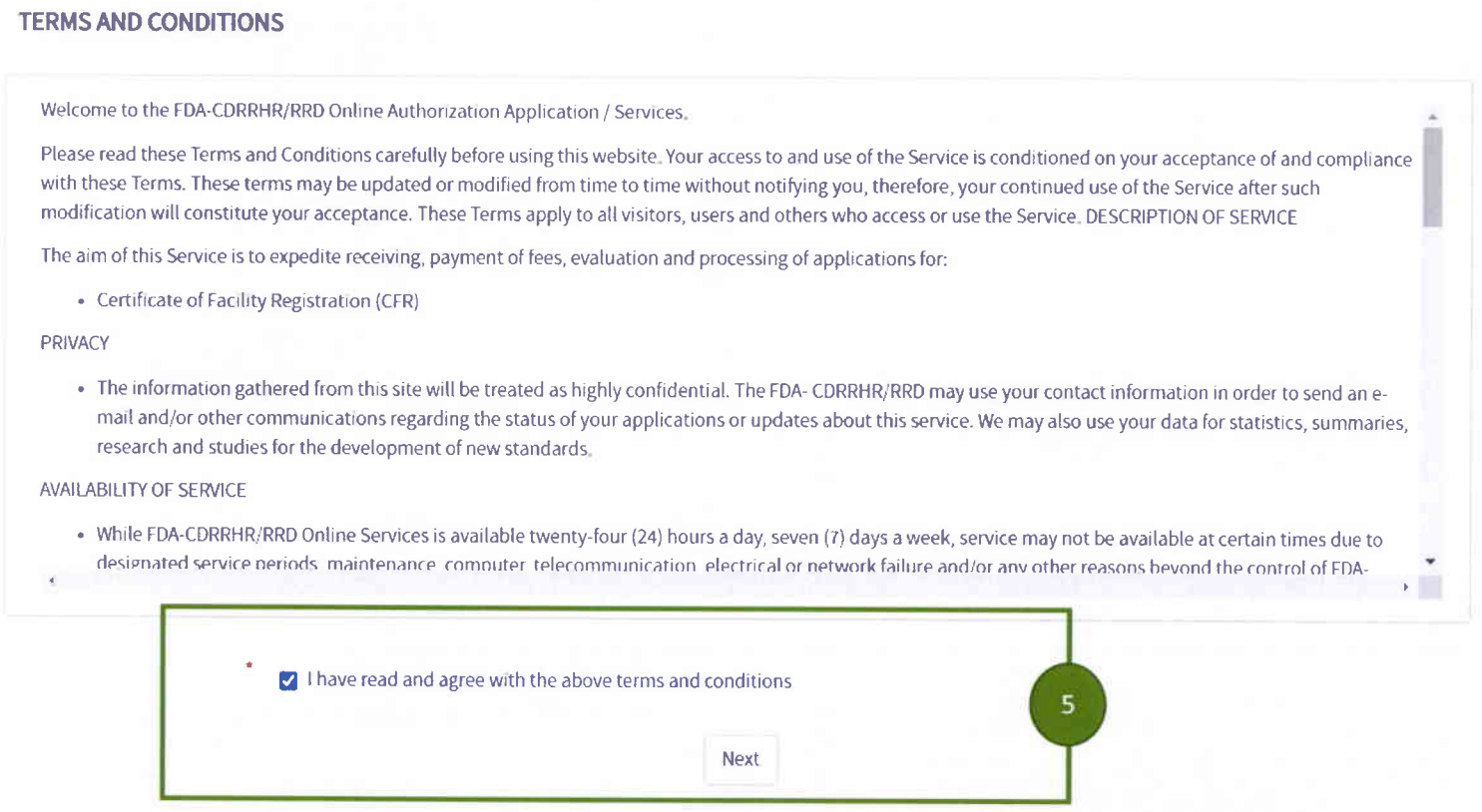
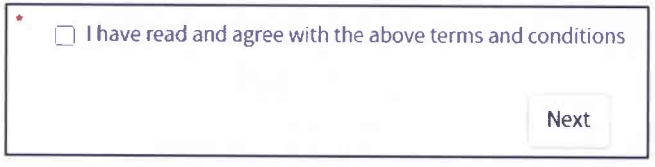


Figure 3. *RRDPortal Terms and Condition.*

STEP 5: Read the Terms and Conditions of using the RRD portal carefully then tick *"I have read and agree with the above terms and conditions"*. Click "Next" to proceed.



General Information Page

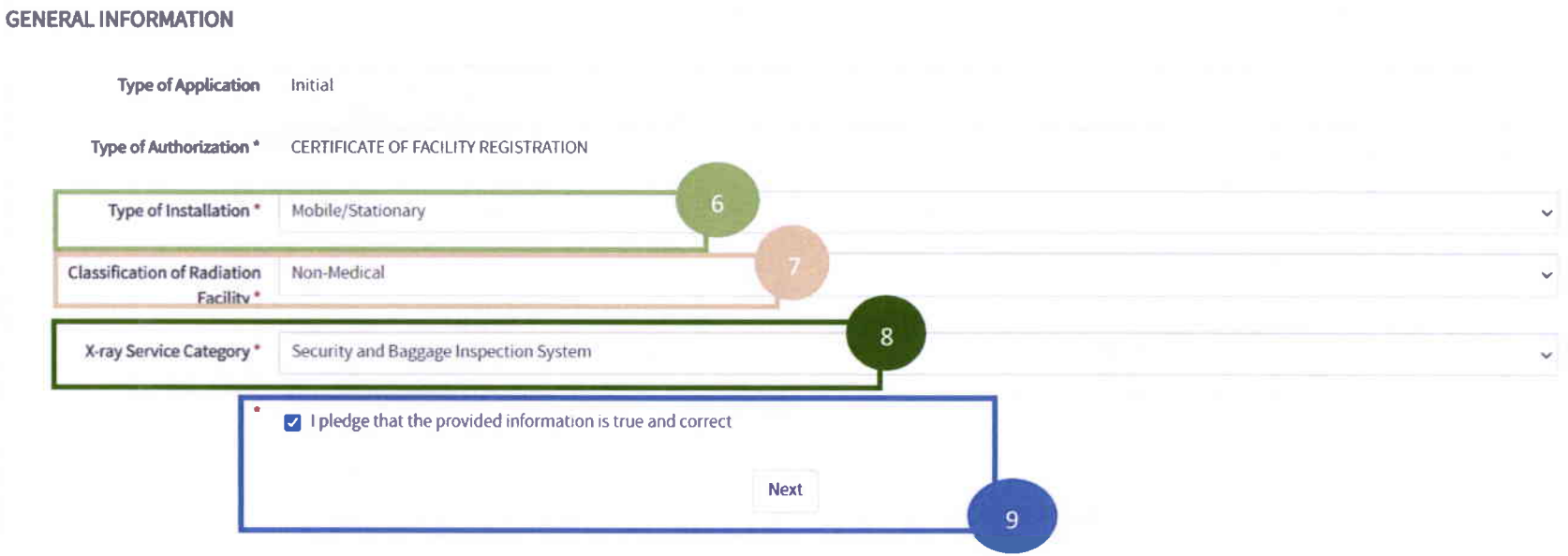
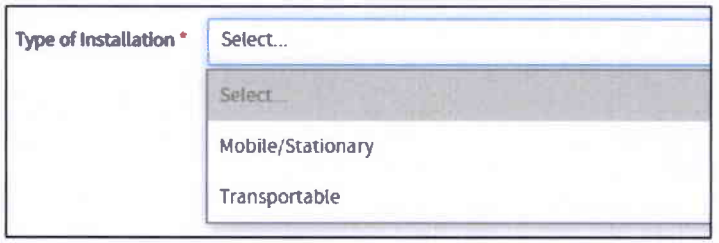


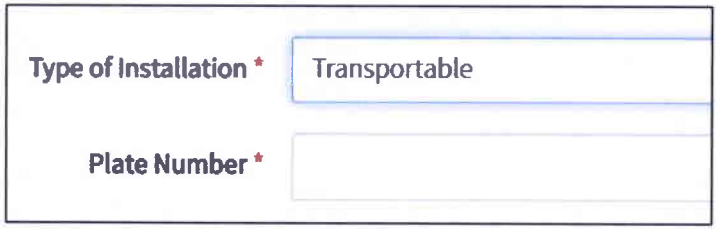
Figure 4. *RRDPortal General Information.*

STEP 6: Select the "Type of Installation" of the x-ray machine.

Options*: "Mobile/Stationary" or "Transportable"*



If ***Transportable*** is selected, indicate the Plate Number of the vehicle



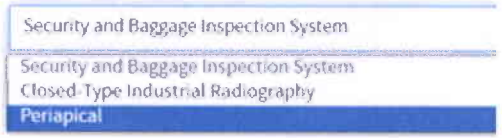
STEP 7: Select the "Classification of Radiation Facility"

Options*: "Medical"* or ***"Non-Medical"***

STEP 8: Select the "X-ray Service Category"

Option 1*:* If ***"Medical"*** Radiation Facility is selected, specify if ***Bone densitometry***

Option 2: If ***"Non-Medical"*** Radiation Facility is selected, specify if ***Security and Baggage Inspection System, Closed-Type Industrial Radiography or Periapical***



STEP 9: Review the information provided then tick *"I pledge that the provided information is true and correct"*. Click "Next" to proceed.

Establishment Information Page

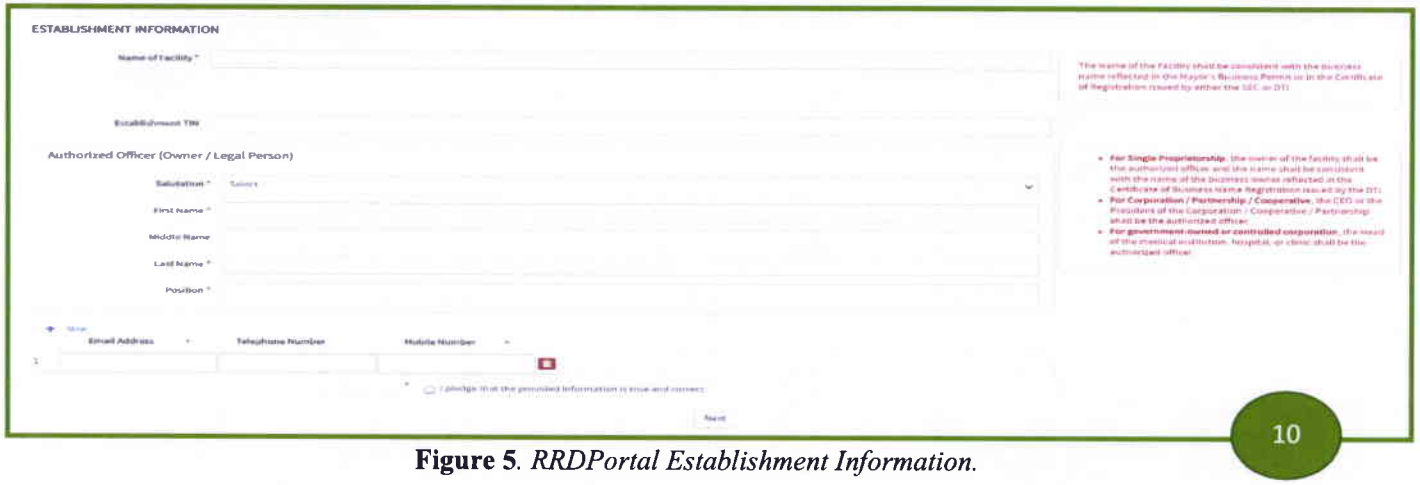


Figure 5. *RRDPortal Establishment Information.*

STEP 10. Fill in the complete and correct details in all the required fields. Review the details then tick "*I pledge that the provided information is true and correct.*". Click "Next" to proceed.

Facility Address Page

Figure 6. *RRDPortal Facility Address.*

STEP 11: Fill in the complete and correct details in all the required fields.

STEP 12: To assist in determining the GPS coordinates, a Map Tool was integrated into the system. To access the Map Tool, click the "Show Map Tool" button. Zoom in to the preset "Blue Pin" to get a closer image of the location of the establishment. The "Blue Pin" may be adjusted to exactly determine the GPS coordinates. Once the location is determined, click the "Submit" button.

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Figure 7. *RRDPortal Map Tool*

Map Page

Figure 8. *RRDPortal Map Tool.*

STEP 14. A map with a closer look at the location of the establishment will be shown for further review and verification. Once satisfied, click the "Next" button to proceed. To make adjustments, click "Previous Step" to return to STEP 13.

List of Personnel Page

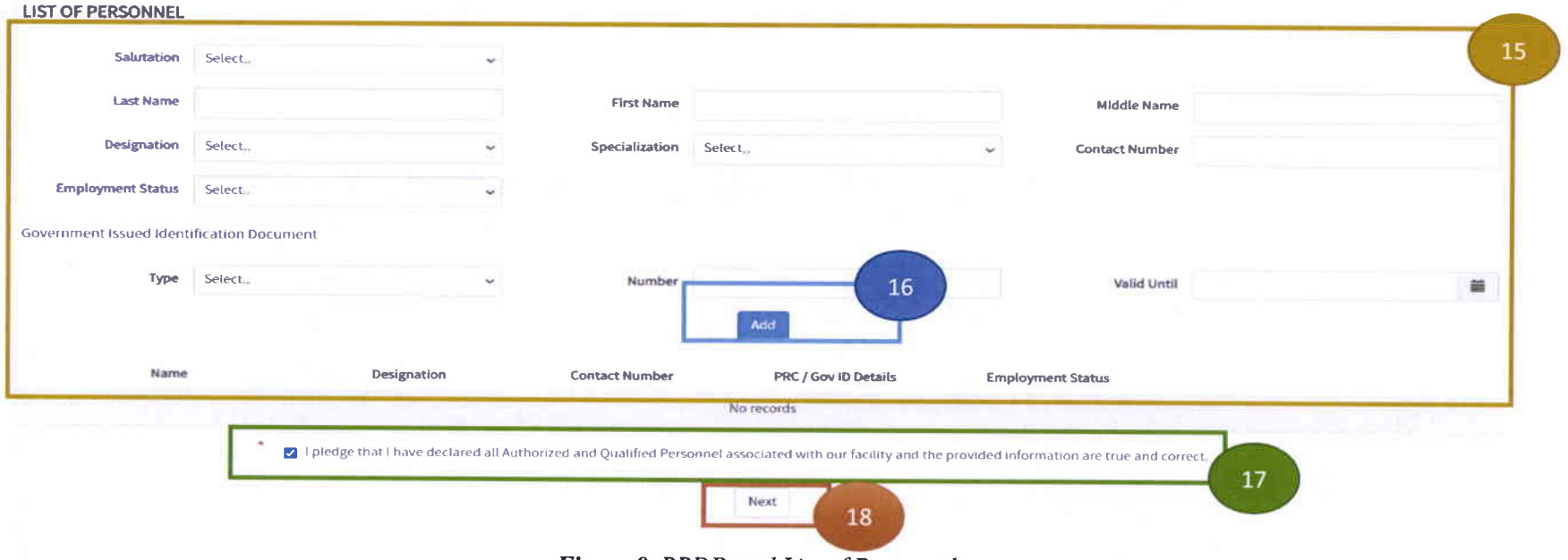


***Figure 9**. RRDPortal List of Personnel.*

STEP 15: Fill in the complete and correct information in all the required fields.

STEP 16: Click the "Add" button to officially register the information of the personnel. Ensure that all employed radiation workers of the facility are registered in the system

STEP 17: Review all the details provided tick *"I pledge that I have declared all Authorized and Qualified Personnel associated with our facility and the provided information are true and correct."*

STEP 18: Click the "Next" button to proceed.

Machine Details Page

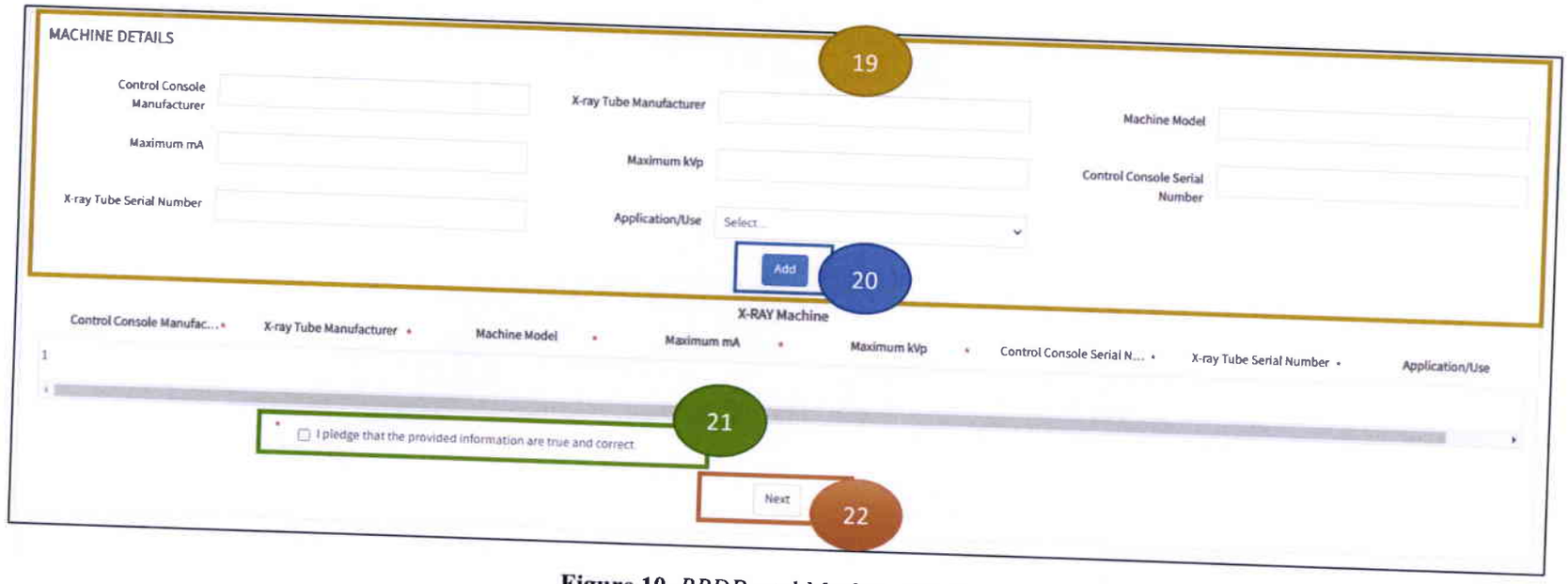


Figure 10. *RRDPortal Machine Details.*

STEP 19: Fill in the complete and correct details in all the required fields.

STEP 20: Click the "Add" button to officially register the details of the x-ray machine. Ensure that all x-ray machines installed or located within the vicinity of the facility are registered in the system.

STEP 21: Review all the details provided then tick *"I pledge that I have declared all x-ray machines installed within and owned by our facility and the provided information are true and correct."*

STEP 22: Click the "Next" button to proceed.

Uploading of Documentary Requirements

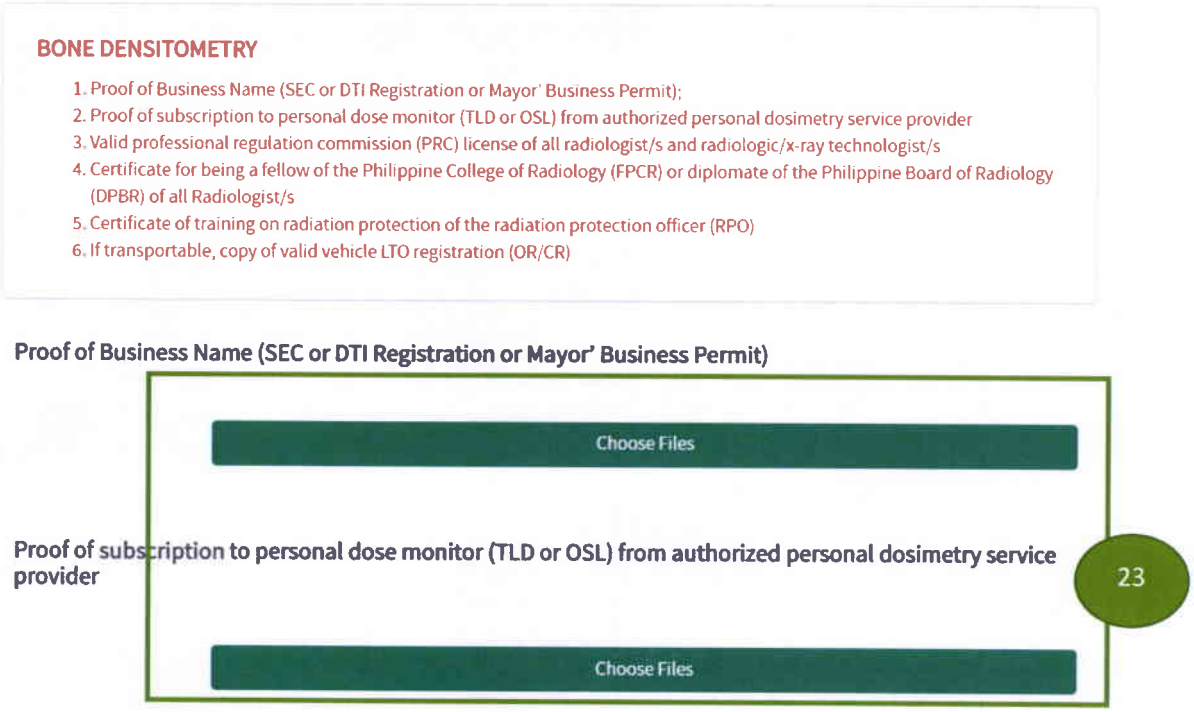


Figure 11a. *The upper portion (center pane) of the RRDPortal Document Requirement Details page.*

STEP 23: To upload the respective documentary requirements, click the "Choose Files" button then locate and select the respective document (in PDF file format) on the computer.

Summary Page

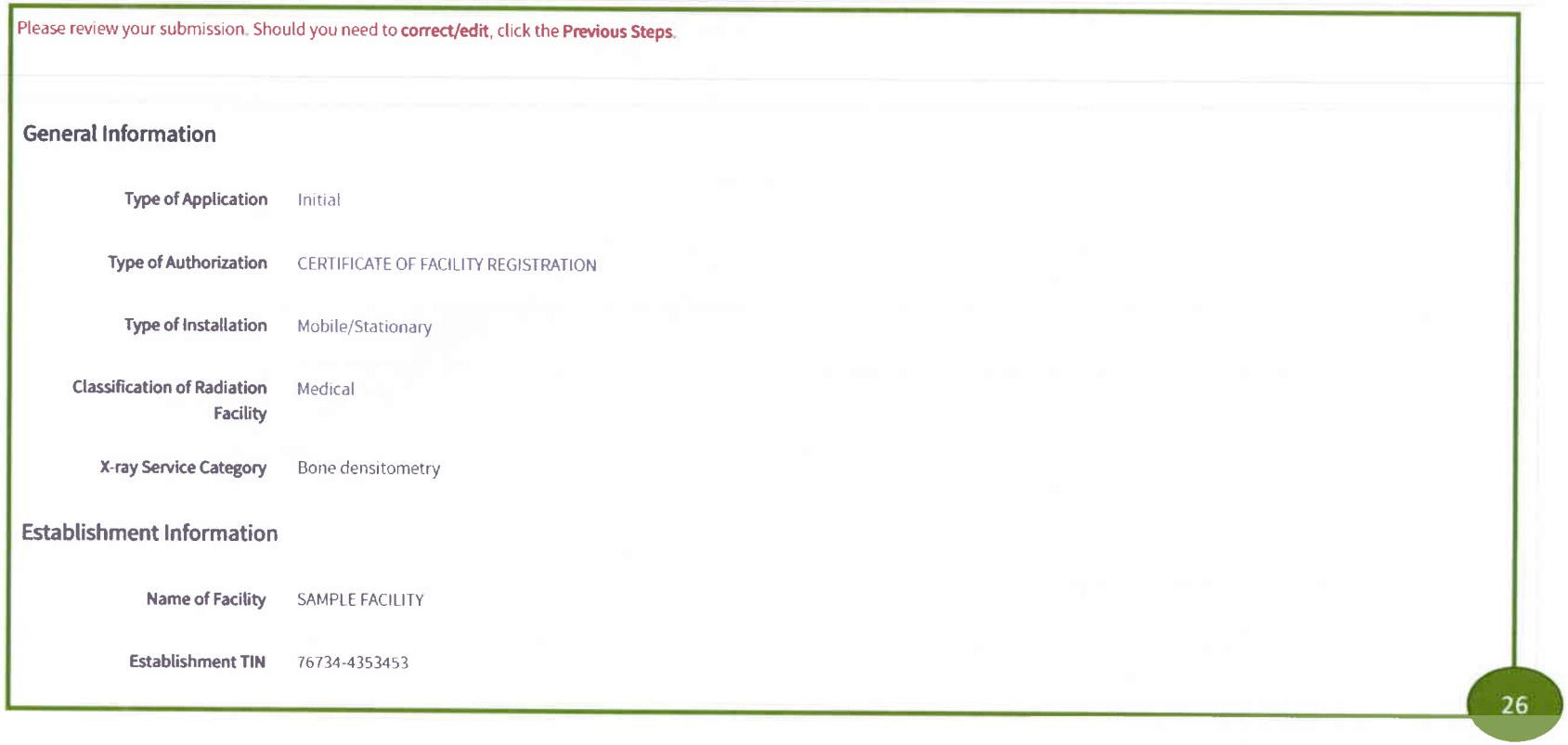


Figure 12a. *The upper portion (center pane) of the RRDPortal Summary Details Page.*

STEP 26: The summary of the application will be shown for the final review. Ensure that all the information and documents provided are complete, true, and correct.

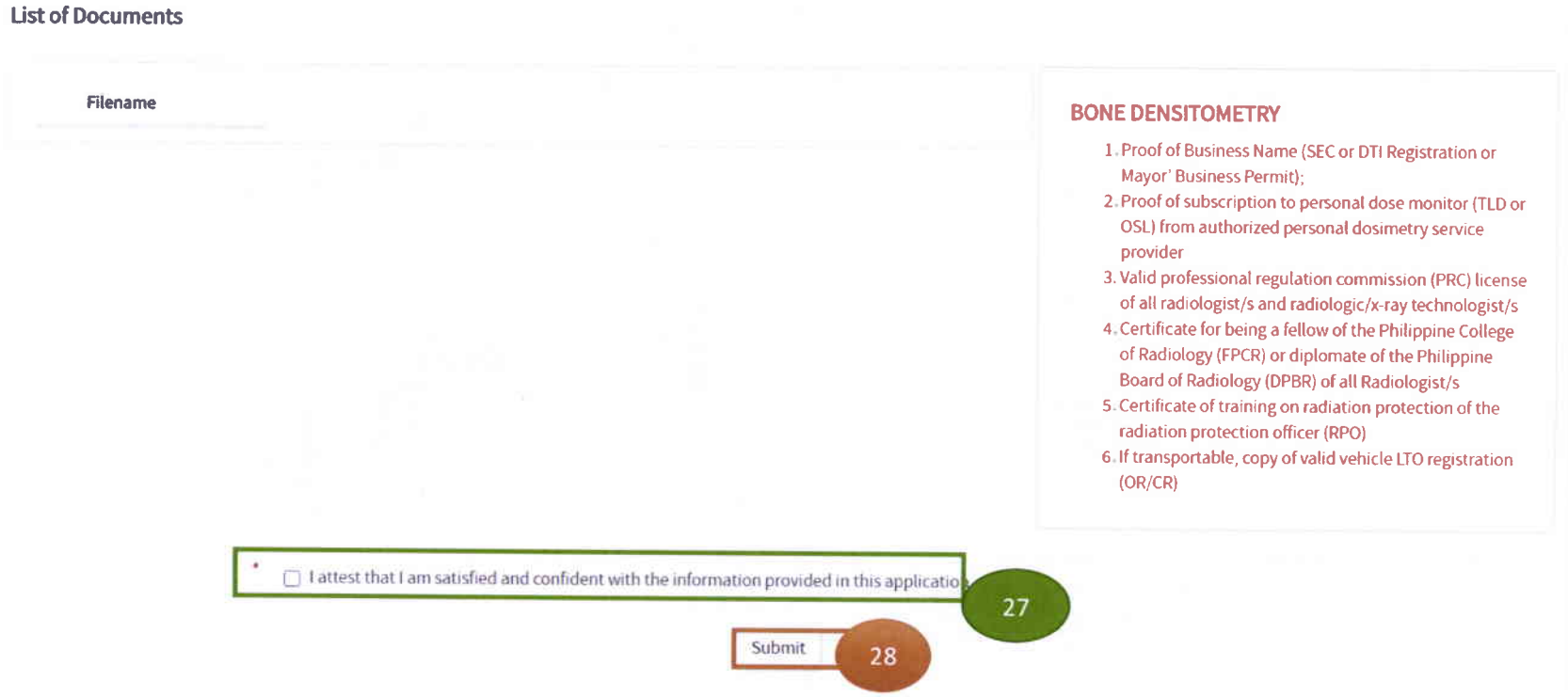
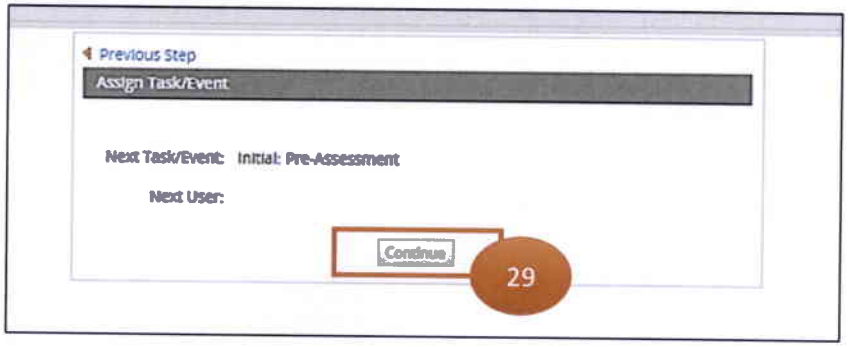


Figure 12b. *The bottom portion (center pane) of the RRDPortal Summary Details Page.*

STEP 27: Once satisfied with the provided information, tick *"I attest that I am satisfied and confident with the information provided in this application."*

STEP 28: Click the "Next" button to submit the application.

END of Application



STEP 29: To officially submit and end the application, click the "Continue" button. The application will be endorsed for pre-assessment and a notification of the result will be sent to the registered email address.