



FDA CIRCULAR
No. **2020-021**

07 AUG 2020

SUBJECT: Guidelines for the Acceptance of Certificate of Safety Evaluation (CSE) Applications for Radiofrequency Radiation (RFR) Facilities through the FDA RRD Portal

I. INTRODUCTION

With the alignment to the provisions of Republic Act 11032 or the “*Ease of Doing Business (EODB) and Efficient Government Service Delivery Act of 2018*”, the FDA sought to re-engineer its authorization processes to streamline and 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 authorization process for radiation facilities under its jurisdiction.

Radiofrequency Radiation (RFR) facilities, such as cell sites/mobile phone base stations, radio, and TV stations, are radiation facilities regulated by the FDA through Republic Act 9711 or the “*FDA Act of 2008*”. DOH AO 2020-0035 includes RFR facilities in the new online authorization process and renames the current RFR evaluation report to a Certificate of Safety Evaluation (CSE). This will automate and streamline the issuance of authorizations by adopting online measures readily accessible to all relevant stakeholders.

II. OBJECTIVES

This Circular aims to provide implementing guidelines to all relevant stakeholders of the new process in the acceptance of applications of CSE for RFR facilities pursuant to DOH AO No. 2020-0035.

III. SCOPE AND COVERAGE

This Circular is issued to all RFR facilities and their authorized representatives for guidance in accessing and utilizing the new online authorization process for radiation facilities.

IV. GUIDELINES

- a. The FDA shall resume the acceptance of applications for RFR Evaluation Reports, now the Certificate of Safety Evaluation (CSE).



- b. All applications shall be accepted, evaluated, and issued through the new FDA Radiation Regulation Division (RRD) portal at <https://rrdportal.fda.gov.ph/> to streamline the issuance process.
- c. For CSE applications, the detailed step-by-step procedure and illustrative guide is annexed hereto as reference and is made an integral part of this issuance.
- d. All processes shall be done in accordance to the general and specific guidelines of DOH AO No. 2020-0035.

V. REPEALING CLAUSE

All issuances, or parts thereof, which are inconsistent with the provisions of this Circular, including FDA Circular No. 2020-006, are hereby repealed, or modified accordingly.

VI. EFFECTIVITY

This circular shall take effect immediately.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX A

GUIDELINES FOR THE REGISTRATION OF USER ACCOUNTS FOR RRDPORTAL



Step 1: Go to <http://rrdportal.fda.gov.ph/>, then click on “Create User Account”.

Step 2: Fill in all the required fields for the user account registration, then click “Submit”.

[[COMPANY LETTERHEAD]]

DATE

The Director General
Food and Drug Administration
Civic Drive, Filinvest City
Alabang, Muntinlupa City

Dear Director General:

We, _____ (Company Name) with business address at _____ hereby authorize _____ (Name of Company Representative) as the registered user/account holder of RRD online authorization services for _____ (License to Operate LTO, Certificate of Facility Registration CFR, Clearance for Customs Release CFCR, Certificate of Safety Evaluation CSE) and shall be responsible for all the applications submitted through the RRD Portal System.

I hereby declare and undertake that all the data and information submitted in connection with this application, as well as other submissions in the future including variations are true, correct and reflect the total information available.

(Owner/Legal Person/Authorized Officer)

SUBSCRIBED AND SWORN to before me, this ____ day of _____ 20__ at _____.

Notary Public

Doc No. _____
Page No. _____
Book No. _____
Series No. _____

NOTE: Authorization Letter shall be duly filled up, printed with the letter head of the company, notarized and then scanned before uploading to the system.

Note: Once your Request for User Account has been approved, the registered Email Address will receive a confirmation email containing the **Username**, **Password**, and the **Validity** of the User Account.

FDA User Account Request Inbox x



FDA PH

to me ▾

Dear Carla Ediza,

We would like to inform you that your Request for User Account has been APPROVED. Please see the details below:

User Account Information

Company Name: Doofenshmirtz Evil Incorporated

Username: FDARRD_0021

Password: KubaQo3P3Wqx

Validity: 24 September 2020

You can now Access the FDA rrdPortal at <http://rrdportal.fda.gov.ph>



Thank You,

CDRRHR-RRD

Food and Drug Administration, Philippines

P.S. This is an Automated Notification Message. Please do not reply.

 Reply

 Forward

Sample email for the **Approved** Request for User Account

FDA User Account Request Trash x



FDA PH

to me ▾

10:15 AM (17 minutes ago)

Dear Carlo Ediza,

We regret to inform you that your Request for User Account for the Doofenshmirtz Evil Incorporated has been DISAPPROVED for the following reason's:

.

Thank You,

CDRRHR-RRD

Food and Drug Administration, Philippines

P.S. This is an Automated Notification Message. Please do not reply.

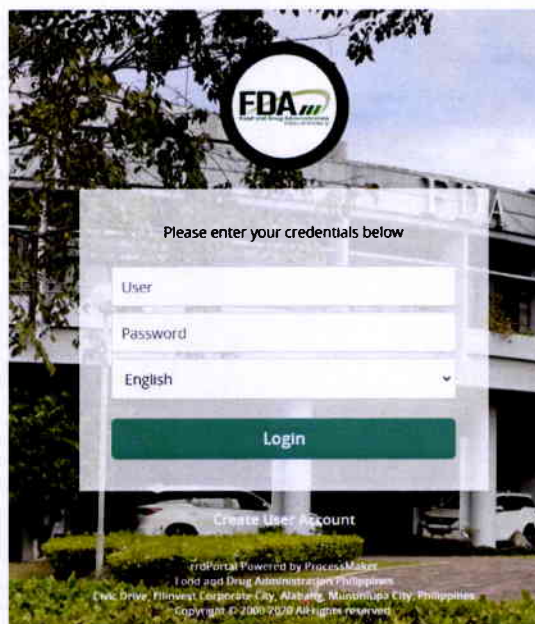
 Reply

 Forward

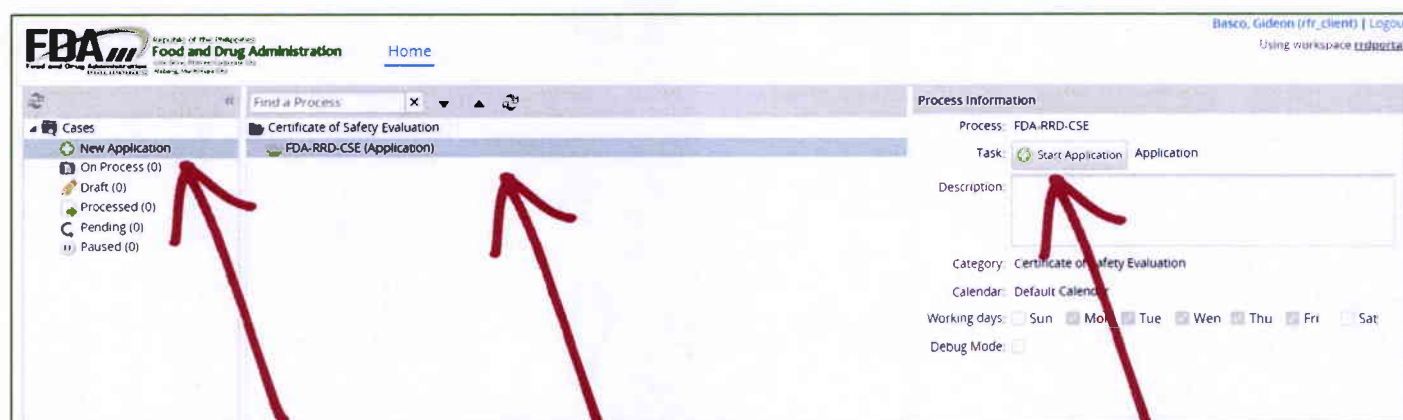
Sample email for the **Disapproved** Request for User Account

ANNEX B

GUIDELINES FOR THE ONLINE APPLICATION OF CERTIFICATE OF SAFETY EVALUATION



Step 1: Go to <http://rrdportal.fda.gov.ph/>, then log in using your Registered User Account.



Step 2: Select "New Application", click on "FDA-RRD-CSE (Application)", and then click "Start Application".

FDA Republic of the Philippines
Food and Drug Administration
1201 Alabang Village, Alabang, Muntinlupa City

Home

Steps: Information Actions Application Notes

Application #: 986 Title: #986

Next Step

TERMS AND CONDITIONS

Welcome to the FDA-CDRHR/RRD Online Authorization Application / Services.

Please read these Terms and Conditions carefully before using this website. Your access to and use of the Service is conditioned on your acceptance of and compliance with these Terms. These terms may be updated or modified from time to time without notifying you, therefore, your continued use of the Service after such modification will constitute your acceptance. These Terms apply to all visitors, users and others who access or use the Service.

DESCRIPTION OF SERVICE

The aim of this Service is to expedite receiving, payment of fees, evaluation and processing of applications for:

- Certificate of Safety Evaluation (CSE) for Non-ionizing Radiation Facility

PRIVACY

- The information gathered from this site will be treated as highly confidential. The FDA-CDRHR/RRD may use your contact information in order to send an e-mail and/or other communications regarding the status of your applications or updates about this service. We may also use your data for statistics, summaries, research and studies for the development of new standards.

AVAILABILITY OF SERVICE

- While FDA-CDRHR/RRD Online Services is available twenty-four (24) hours a day, seven (7) days a week, service may not be available at certain times due to designated service periods, maintenance, computer, telecommunication, electrical or network failure and/or any other reasons beyond the control of FDA-CDRHR/RRD.

☐ I have read and agree with the above terms and conditions

Next

Step 3: Read the Terms and Conditions carefully. Tick the checkbox that says “I have read and agree with the above terms and conditions”, then click “Next”.

FDA Republic of the Philippines
Food and Drug Administration
1201 Alabang Village, Alabang, Muntinlupa City

Home

Steps: Information Actions Application Notes

Application #: 986

Application #: 986 Title: RRD-CSE-900000000982

Next Step

General Information

Classification of RFR Facility *

Mobile Telephone Base Station

Type of Application *

Select

Type of Antenna Installation *

Select

☐ I pledge that the provided information are true and correct.

Next

Step 4: Fill in all the required fields for General Information, tick the check box that says “I pledge that the provided information are true and correct.”, then click “Next”.

FDA Food and Drug Administration

Home

Application # 986 Title: RRD-CSE-900000009862

Details of the Contractor

Telecommunications Company * Enter the name of the telecommunications company

Contractor Name * Enter the name of the contractor

Contractor Address * Enter the contractor's address

Contact Number * Enter the contractor's contact number

Contractor's Authorized Officer

Name * Enter the contractor's authorized officer

Contact Number * Enter the contractor's authorized officer's contact number

Designated RFR Safety Officer

Surname Enter the surname of the contractor's designated RFR Safety Officer

First Name Enter the first name of the contractor's designated RFR Safety Officer

Middle Name Enter the middle name of the contractor's designated RFR Safety Officer

☐ I pledge that the provided information are true and correct.

Next

Step 6: Fill in all the required fields for the Contractor Details, tick the check box that says "I pledge that the provided information are true and correct." then click "Next".

FDA Food and Drug Administration

Home

Application # 986 Title: RRD-CSE-900000009862

List of Antenna

Do you have Link Antenna? * Select...

☐ I pledge that the provided information are true and correct.

Next

FDA Food and Drug Administration

Home

Application # 986 Title: RRD-CSE-900000009862

List of Antenna

Link Antenna

Transmit Frequency (MHz)

Antenna Brand

Transmitted Power (watts)

Diameter for parabolic antenna/dimension for panel antenna, meters

Received Frequency (MHz)

Antenna Model

Antenna Height (AGL), meters

Antenna Gain (dBi)

Type of Installation

☒ I pledge that the provided information are true and correct.

Next

Step 7: For the List of Antenna, select whether you have Link Antenna or not, if yes, fill in all the required fields for the Link Antenna Specs, tick the checkbox that says "I pledge that the provided information are true and correct.", then click "Next".

FDA Republic of the Philippines
Food and Drug Administration
One Drive, Alabang Corporate City
Alabang, Muntinlupa City

Basco, Gideon (rfr_client) | Logout
Using workspace rrdportal

Home

Steps Information Actions Application Notes

Application #: 986

Application #: 986 Title: RRD-CSE-900000009862

Previous Step Next Step

NOTE:
Please provide the scanned copy of the following documents:

+ New

Floor Plan for Indoor Antenna

ELEVATION DRAWING

Elevation Drawing and NTC Temporary Permit for Broadcasting Network

1 Choose File

☐ I pledge that the provided information are true and correct.

Next

Step 10: For the documentary requirements, click on the  icon to choose the file you will upload, tick the check box that says "I pledge that the provided information are true and correct." then click "Next".

FDA Republic of the Philippines
Food and Drug Administration
One Drive, Alabang Corporate City
Alabang, Muntinlupa City

Basco, Gideon (rfr_client) | Logout
Using workspace rrdportal

Home

Steps Information Actions Application Notes

Application #: 986 Title: RRD-CSE-900000009862

Previous Step Next Step

Please review your submission. Should you need to correct/edit, click the Previous Step.

General Information

Classification of RFR Facility: Mobile Telephony Base Station
Type of Application: Upgrade Site
Type of Antenna Installation: Outdoor Antenna

Details of the Contractor

Telecommunications Company: Sample Telecom
Contractor/Sub-contractor Name: Sample Contractor
Contractor/Sub-contractor Address: Sample Address
Contract Number: 9823456789
Contractor Sub-contractor's Authorized Officer:
Name: Sample Full Name
Contract Number: 9823456789
Designated RFR Safety Officer:
Surname: Sample
First Name: Sample
Middle Name: Sample

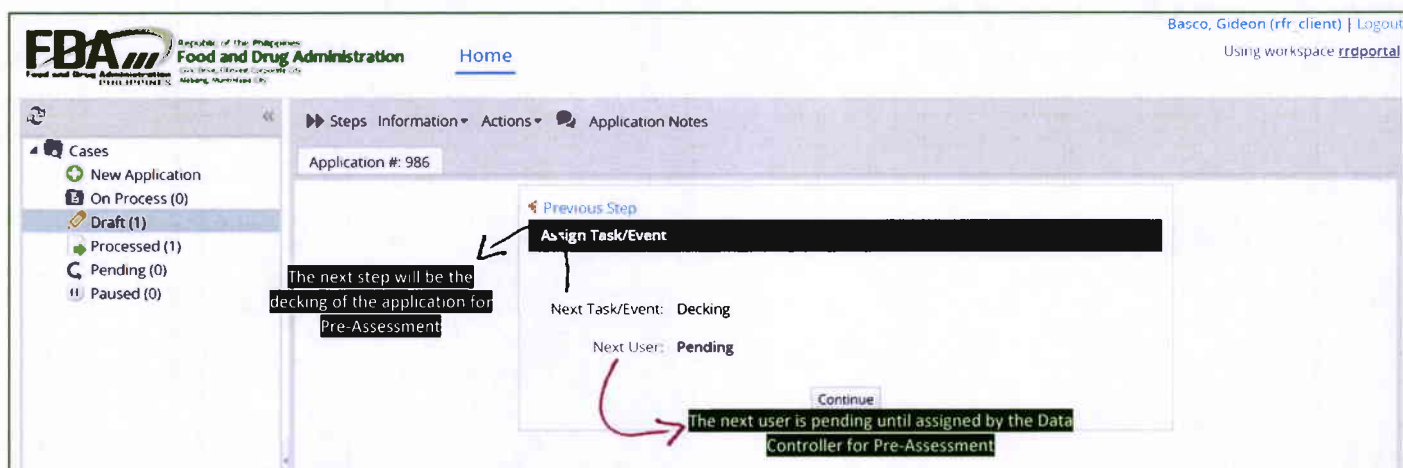
Site Address

Specific Site Name and/or ID: SAMPLE_SITE_ID_12345
Collocated? Yes
Site Address: Brgy. Dava, Lupa, Batangas
Region: Region IV-A
Province: Batangas
City: Lupa City
Zip Code: 4217
GPS Latitude (at least 8 decimal): 14.3323897774270
GPS Longitude (at least 8 decimal): 121.1362539062501

Antenna Grid

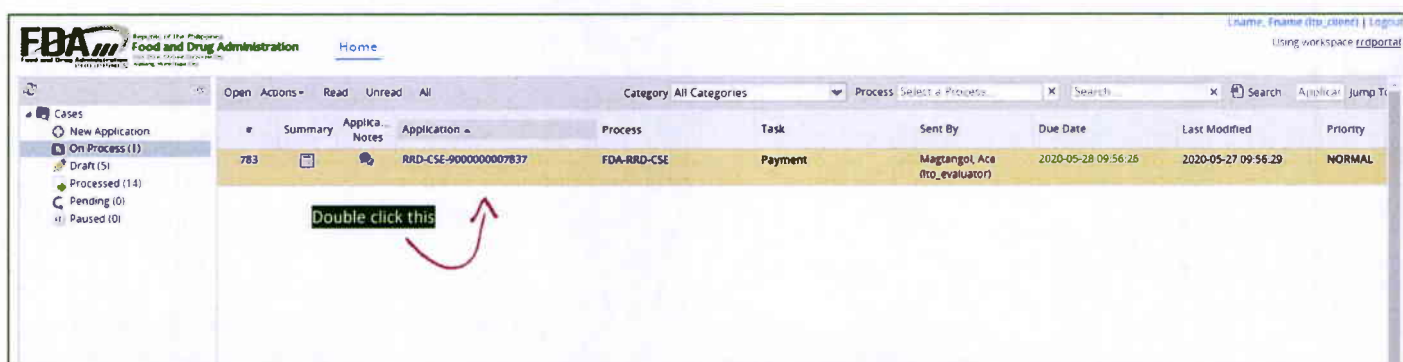
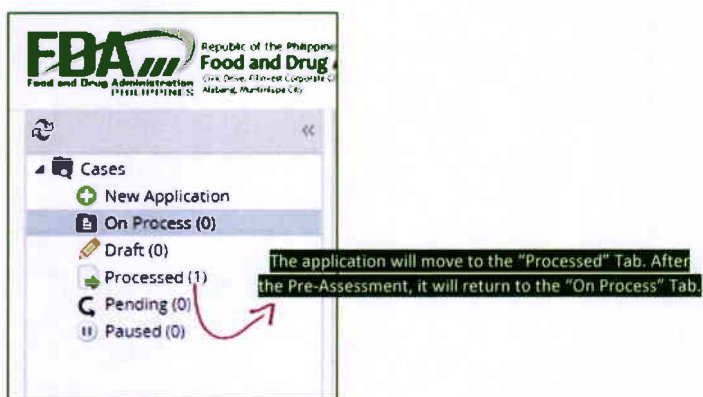
Antenna Grid

Step 11: Check the application summary. Click "Previous Step" to correct if there are any corrections, if none, click "Next".



Step 12: Check the application summary. Click “Previous Step” to correct if there are any corrections, if none, click “Next”.

The next step will be the decking of the application for Pre-Assessment. Once it is done, you will receive a notification together with your Order of Payment.



Step 13: Once the Pre-Assessment is done, you will receive the application on your “On Process” tab. Double click the application number to open.

FDA Food and Drug Administration
Home Designer Dashboards Admin

Application # 994 Title RRD-CSE-9000000009947

Click this to download the file

Click this to print the file

Please click the "Next" Button after the payment was completed, then upload the Official Receipt or Validated LandBank OnCall slip as proof of payment. Payment options is thru FDA Cashier or Landbank OnCall Payment.

Processmaker

Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

ORDER OF PAYMENT

GENERAL INFORMATION


Account Code:	RRD-CSE-9000000009947
Product Center:	Center for Device Regulation, Radiation Health, and Research
Authorization:	Certificate of Safety Evaluation
Payable to Account Number:	0392-2220-30
Payable to Account Name:	FDA Devices Clearing Account

ESTABLISHMENT INFORMATION

Company:	Dfg
Contractor / Sub-contractor:	Dfg
Owner:	lto_evaluator

Next

Step 14: Download and print the system generated Order of Payment. Pay at the nearest branch of LandBank of Philippines or at the FDA Cashier. Click "**Next Step**" to upload proof of payment.

 Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

FDA Food and Drug Administration
ESTABLISHED 1972

ORDER OF PAYMENT

GENERAL INFORMATION

Account Code:	RRD-CSE-9000000009947
Product Center:	Center for Device Regulation, Radiation Health, and Research
Authorization:	Certificate of Safety Evaluation
Payable to Account Number:	0392-2220-30
Payable to Account Name:	FDA Devices Clearing Account

ESTABLISHMENT INFORMATION

Company:	Dfg
Contractor / Sub-contractor:	Dfg
Owner:	lto_evaluator

PAYMENT DETAILS

Application Fee:	Php 900.00
Surcharge (if any):	Not Applicable
Legal Research Fund (LRF):	Not Applicable
Total Amount:	Php 900.00

Sample Order of Payment

FDA Republic of the Philippines Food and Drug Administration

Home

Application #: 783 Title: RRD-CSE-900000007837

Previous Step Next Step

UPLOAD RECEIPT HERE

+ New

PAYMENT TYPE

Upload Here

Select Choose File

PAYMENT TYPE

LANDBANK ONCOLL

FDA CASHIER

LANDBANK ONCOLL

I pledge that the provided information are true and correct

Submit

Step 15: Upload the **Official Receipt**, if you paid at the **FDA Cashier**, or **LandBank Oncoll Payment Slip** verified by the bank teller if you paid at any branch of **LandBank of the Philippines**. Tick the check box that says **"I pledge that the provided information are true and correct."** then click **"Submit"**.

FDA Republic of the Philippines Food and Drug Administration

Home

Application #: 783

Previous Step

Assign Task/Event

Next Task/Event: Payment Verification

Next User: Pending

The next user is pending until proof of payment was received and verified by Cashier

Next Task/Event: Application Evaluation

Next User: Magtangol, Ace

Continue

Step 16: After uploading your Receipt/LandBank Oncoll Payment Slip, your application will proceed to the **Cashier** for verification of payment and to the **Evaluator** for further evaluation.

FDA Bureau of the Philippines Food and Drug Administration

Home

Open: Started by Me | Completed by Me | All

Category: All Categories | Process: Select a Process | Status: All Status | Search | Apply | Jump To

#	Summary	Application Number	Process	Task	Current User	Last Modified	Priority
783		RRD-CSE-9000000007837	FOA-RRD-CSE	Application Quality Assurance	ito_qa_ito_qa	2020-05-27 10:31:03	To Do

Click here to see the details

Summary

General Information | Uploaded Documents | Generated Documents

Application Properties

Process	FDA-RRD-CSE
Application Title	RRD-CSE-9000000007837
Application Number	783
Application Status	To do
Application UID	9478193415ecda90bb3fce4076567303
Creator	Frame LName
Create Date	2020-05-27 07:40:50
Last Update	2020-05-27 10:31:03
Application Description	

Current Task(s) Properties

Task	Application Quality Assurance
Current User	ito_qa_ito_qa
Task Delegate Date	2020-05-27 10:31:02
Task Init Date	null

You can see the details and updates of your application in the "Processed" tab on the left side of the system.

FDA Bureau of the Philippines Food and Drug Administration

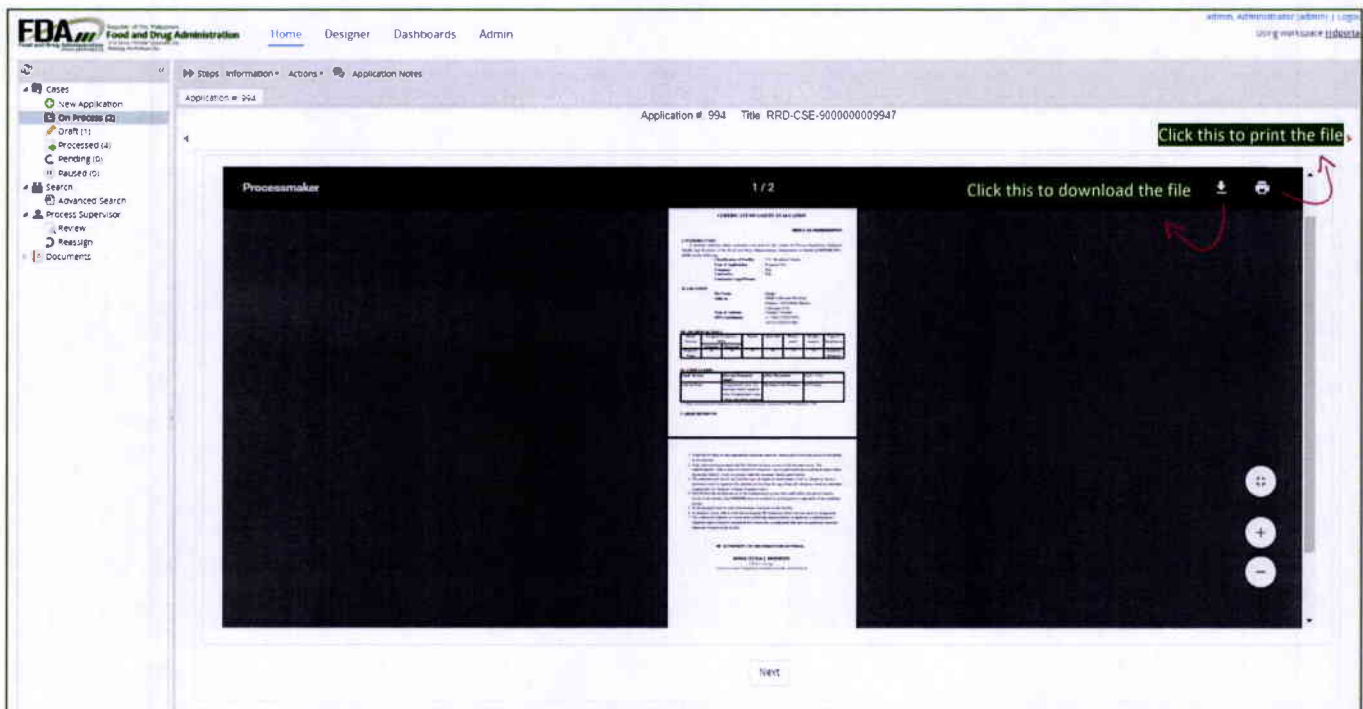
Home

Open: Actions | Read | Unread | All



Category: All Categories | Process: Select a Process | Search | Apply | Jump To

#	Summary	Application Number	Process	Task	Sent By	Due Date	Last Modified	Priority
783		RRD-CSE-9000000007837	FDA-RRD-CSE	Download Result (Client)	carthy_director carthy_director lcarthy_director	2020-05-28 10:47:43	2020-05-27 10:47:43	NORMAL


Step 17: Once the evaluation of your application is done, you will receive a message in your inbox. Click "On Process" then double click the application number.



Step 18: You will see the approved Certificate of Safety Evaluation. You can download and print it in A4 size bond paper. Then click "Next".

 <div> <p>Republic of the Philippines Department of Health Food And Drug Administration Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City</p> </div> 		<p>CERTIFICATE OF SAFETY EVALUATION</p> <p>RRD-CSE-9000000009947</p>				
<p>I. INTRODUCTION</p> <p>A desktop radiation safety evaluation was done by the Center for Device Regulation, Radiation Health, and Research of the Food and Drug Administration, Department of Health (CDRRHR-FDA-DOH) on the following:</p>						
<p>Classification of Facility</p>		<p>: T.V. Broadcast Station</p>				
<p>Type of Application</p>		<p>: Proposed Site</p>				
<p>Company</p>		<p>: Dfg</p>				
<p>Contractor</p>		<p>: Dfg</p>				
<p>Contractor Legal Person</p>		<p>:</p>				
<p>II. LOCATION</p>						
<p>Site Name</p>		<p>: dfgdfl</p>				
<p>Address</p>		<p>: Dfgdf, Caloocan (Kaybiba / Deparo), 1420, Metro Manila- Caloocan, NCR</p>				
<p>Type of Antenna</p>		<p>: Outdoor Antenna</p>				
<p>GPS Coordinates</p>		<p>: 15.728813770533979, 120.87158203125001</p>				
<p>III. TECHNICAL DATA</p>						
Band/ Service	Assigned Frequency, MHz	Brand	Gain, dBi	Power, watt/s	Height, meter/s	Type of Installation
	Transmit	Received				
Point-to-Point	34	34	34	34	34	Aesthetic Mounted
<p>IV. CONCLUSION</p>						
Band/ Service	Relevant Exposure Limits*	Safety Parameter	Safety Value			
Point-to-Point	Occupational Limit: 10 Watts per meter squared Non-Occupational Limit: 2 Watts per meter squared	Minimum Safe Distance	26.07 meter			
<p><small>* based on International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines, 1998</small></p>						
<p>V. REQUIREMENTS</p>						
<p>1. A perimeter fence or any appropriate structure must be constructed to prevent access of the public to the antenna.</p>						
<p>2. Only authorized personnel shall be allowed to have access to the antenna tower. The radiofrequency source must be turned off whenever service personnel are working in areas where the power density levels are greater than the exposure limits stated above.</p>						
<p>3. The antenna must not be activated in case of repair or maintenance work or whenever service personnel need to approach the antenna at less than the specified safe distances from the antennas. (Applicable for Outdoor Cellular Antennas only)</p>						
<p>4. Should there be modifications in the transmission system that could affect the power density levels in the facility, the CDRRHR must be notified in writing prior to operation of the modified design.</p>						
<p>5. Warning signs must be placed at strategic locations in the facility.</p>						
<p>6. A radiation safety officer who has undergone RF radiation safety seminar must be designated.</p>						
<p>7. The contractor/supplier or owner must undertake measurements to generate a radiofrequency radiation map to identify enough points where the occupational and non-occupational exposure limits are located in the facility.</p>						
<p>BY AUTHORITY OF THE DIRECTOR-GENERAL:</p>						
<p>MARIA CECILIA C. MATIENZO Office-in-Charge Center for Device Regulation, Radiation Health, and Research</p>						

Sample of the approved Certificate of Safety Evaluation



Republic of the Philippines

Food and Drug Administration

Quezon City, Alameda Corridor City
Alabang, Muntinlupa City

Lname, Fname (lto_client) | Logout

Using workspace **rdportal**

Home

Steps

Application #: 783

Previous Step

End of process

Next Task/Event: End of process

Last Employee: Lname, Fname

Finish

Step 19: You will reach the end of the process. Click “Finish” to complete the application.

Note: Be reminded that the completed application will be gone in your “On Process”. You will see it in the “Processed” tab.