


Journey of a Medical Device Products: Roadmap to Philippine Market v2.0

By :

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Regulatory Intelligence Committee



A photograph of a red classic convertible car driving on a multi-lane highway. The car is in the left lane, moving away from the viewer. The highway has white lane markings and a guardrail on the right. The background consists of dense green trees and a blue sky with scattered white clouds. Handwritten white annotations are overlaid on the image: a speech bubble above the car, a note on the left with an arrow pointing to the car, and a long arrow on the right pointing towards the horizon with thought bubbles above it.

Is this the way
to FDA ?

Am I on the
right route in
obtaining product
registration ?

Presentation Topics

“What are the **latest updates on medical device registration?**”

“Are there any other **regulatory agencies** that I have to know about?”

“What are the **regulatory processes** that I have to know prior to medical device distribution / market availability?”



What to do ?



Latest Issuance on Licensing Establishments:

FDA Circular No. 2021- 021

Subject: Guidelines on the Licensing of Retailers of Medical Devices in the Philippines

Issuance: 07 October 2021

Effectivity: September 2023

New Regulatory Requirements for Medical Devices

is based on the

**Administrative Order
2018-0002**

issued by DOH on 26 January 2018



Guidelines Governing the Issuance of an Authorization for Medical Device based on the ASEAN Harmonized Technical Requirements

Medical Device - means any **instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent** and **calibrator, software, material** or other similar or related article:

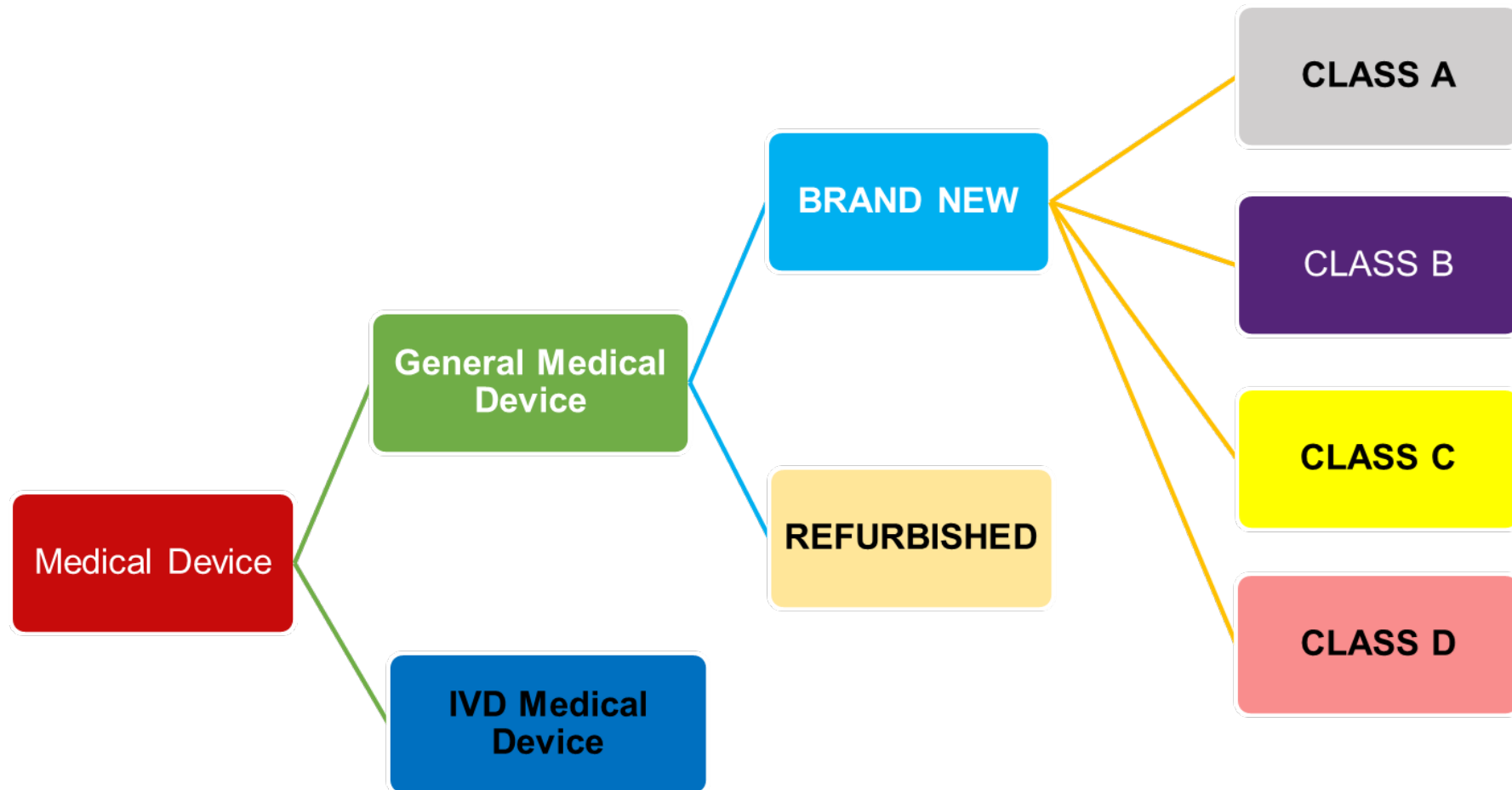
- intended by the manufacturer/product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
 - diagnosis, prevention, monitoring, treatment or alleviation of diseases;
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 - investigation, replacement, modification or support of the anatomy or of a physiological process;
 - supporting or sustaining life;
 - control of conception;
 - disinfection of medical devices;
 - providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;and
- which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.



Medical Device definition based on A.O. 2018-0002:

*Guidelines Governing the
Issuance of an Authorization for a
Medical Device based on the
ASEAN Harmonized Technical
Requirements*

OVERVIEW OF MEDICAL DEVICE (FDA) based on A.O. 2018-0002



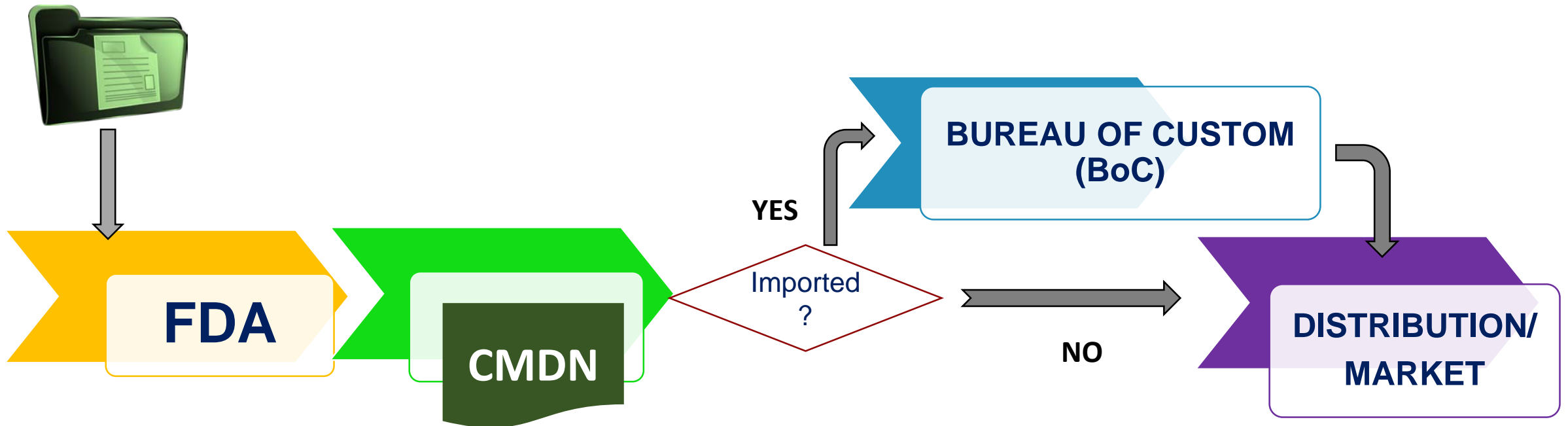
Released Date	Subject
26 Jan 2018	Administrative Order No. 2018-002 : Guidelines Governing the Issuance of an Authorization for Med Device based on ASEAN Harmonized Technical Requirements
23 Jan 2020	FDA Circular No. 2020-001 : Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements
04 Jan 2021	FDA Circular No. 2020-001-A : Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements"
04 Jan 2021	FDA Circular No. 2021-001 : Hierarchy of Product Standards for Medical Devices to be Complied with Notification/Registration Purpose
04 Jan 2021	FDA Circular No. 2021-002 : Full Implementation of Administrative Order No. 2018- 0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"
09 Aug 2021	FDA Circular No. 2021-002-A : Addendum to FDA Circular No. 2021-002 Re: Full Implementation of Administrative Order No. 2018- 0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"
16 Aug 2021	FDA Circular No. 2021-017 : Reference List of Class A Medical Devices
21 Aug 2021	FDA Circular No. 2021-002-B: Amendment to FDA Circular No. 2021-002 entitled Addendum to FDA Circular NO. 2021-002 RE: “Full Implementation of Administrative Order No. 2018- 0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"
27 Sep 2022	FDA Circular No. 2022-008 : Abridged Processing of Application for Registration of Medical Devices approved by the National Regulatory Authority of any ASEAN Member Country
29 Mar 2023	FDA Circular No. 2021-002-C: Guidelines on the Regulatory Flexibility for Class B, C and D Medical Devices that are Not Included in the List of Registrable Medical Devices Based on FDA Circular No. 2020-001-A entitled “Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order NO. 2018-0002 “Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements”

PROCESS MAP ?



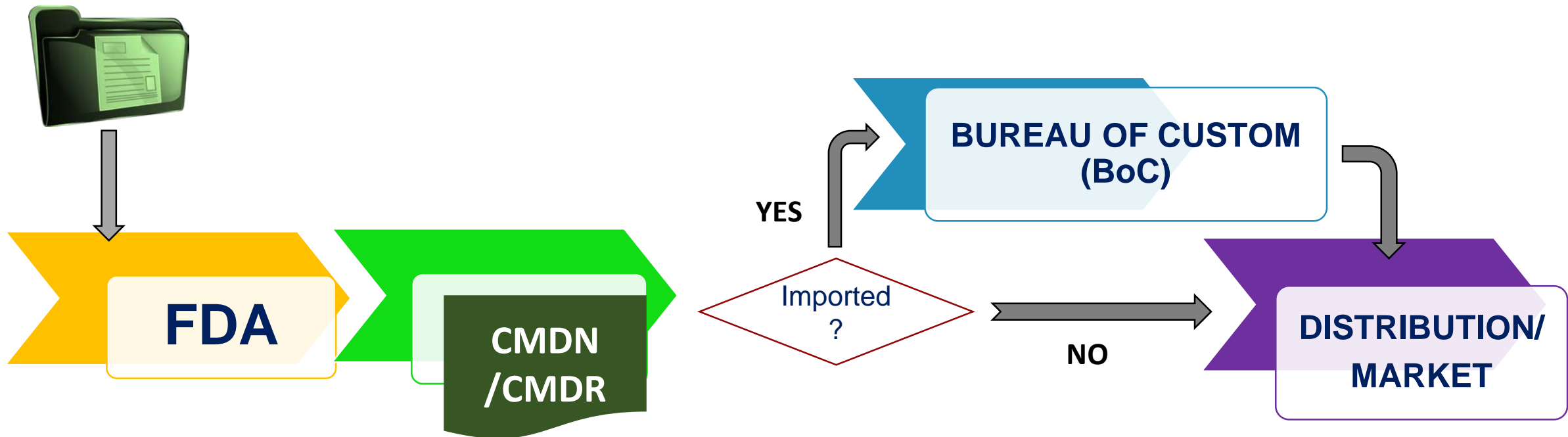
PROCESS MAP for MEDICAL DEVICE PRODUCTS

Medical Device Product Class A *(FDA Circular 2021-0017 Reference List of Class A Medical Device)*



PROCESS MAP for MEDICAL DEVICE PRODUCTS

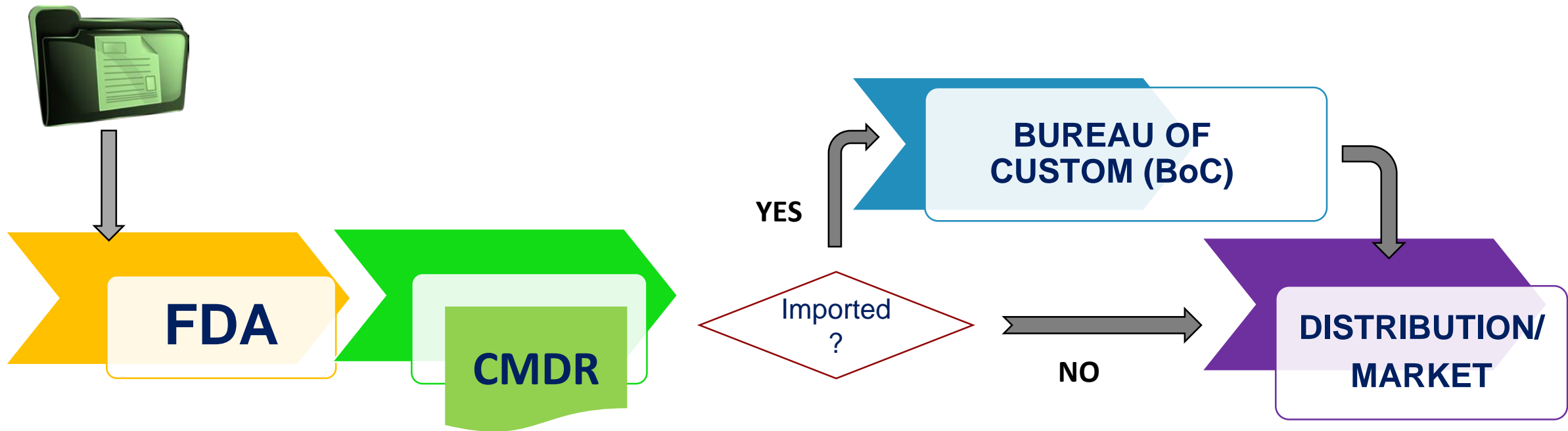
Medical Device Product Class B, C, D * – **NOT** included in the current List of Registrable Medical Devices* based on FC No. 2021-001-A



* FDA Circular 2021-002-C Regulatory Flexibility for Class B, C and D Medical Devices

PROCESS MAP for MEDICAL DEVICE PRODUCTS

Medical Device Product Class B, C, D – **INCLUDED** current List of Registrable Medical Devices**



* A.O. 2018-0002– *Guidelines Governing the Issuance of an Authorization for Medical Device based on ASEAN Harmonized Technical Requirements*

CMDN and CMDR Application Process

RISK CLASS	APPLICATION TYPE	TIMELINE/ FEES / PROCESS/ VALIDITY				
CLASS A	CMDN (thru e-Portal)	Timeline: 20 working days Based on Citizen Charter	Fees to be Paid: Php 7,575 + 1% LRF	Initial Filing : Thru E-portal	Validity of Certificate: 5 years	Renewal Pathway: Same
CLASS B, C, D	CMDR Email with the Google Drive Dossier Link	Timeline: 69 (B) -97 (C-D) working days Based on Citizen Charter	Fees to be Paid: Php 7,575 + 1% LRF	Renewal Filing : Email & Share Google Link Drive	Validity of Certificate: 5 years	Renewal Pathway: Same

Clearance for Customs Release (CFCR) Process - Medical Equipment

Radiation Emitting Device?

CFCR Requirements
Completion

CFCR Application
with FDA

Certificate of
Customs Release

Ionizing Radiation Device:

X-ray

Non Ionizing: Ultrasound

- Legalized FSC or CFG
- Product Brochure or Data sheet
- Commercial Invoice
- Admin Docs – LTO, Business Permit
- Demo Guarantee Letter (if demo)
- If overseas product registration is pending authentication, notarized promissory note

Maximum of 7 days

Release of Permit



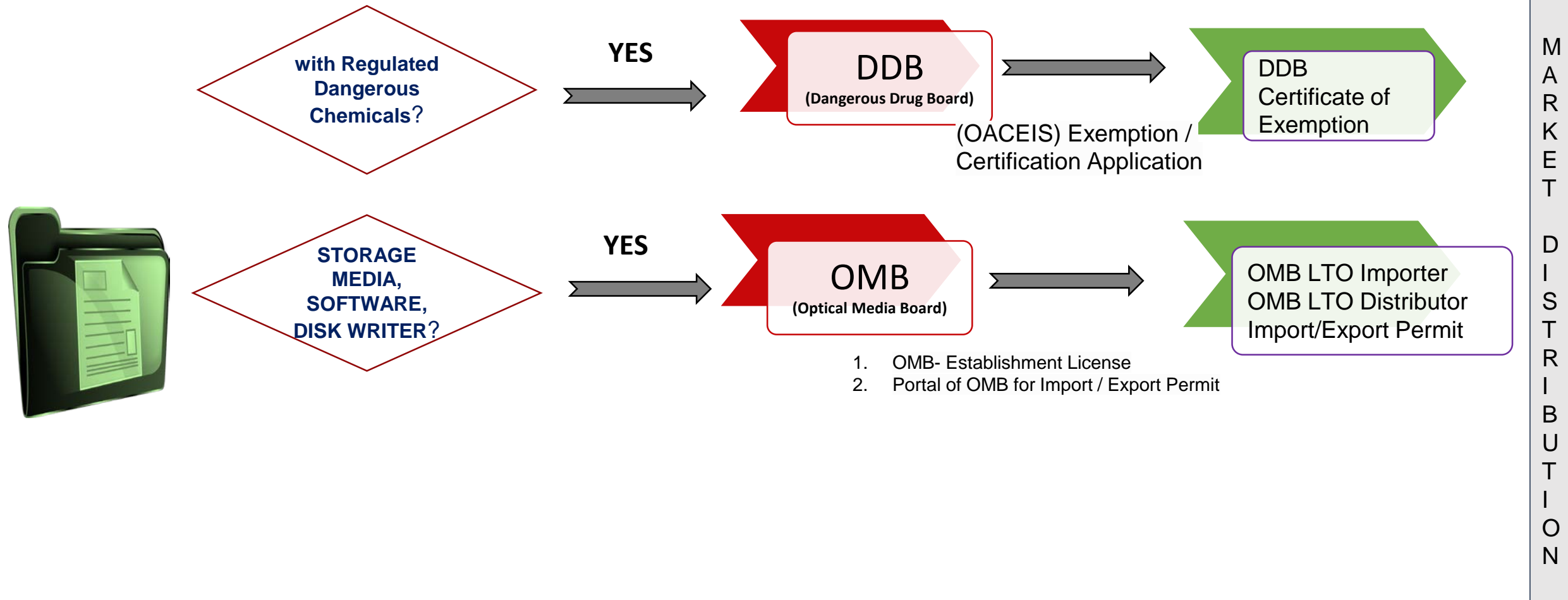
Other
Regulatory
Agencies :
DOH, PNP,
NTC



WHERE SHOULD
I GO ?



PROCESS MAP with other REGULATING AGENCIES



OMB

Optical Media



CD, DVD, etc.

Storage Device



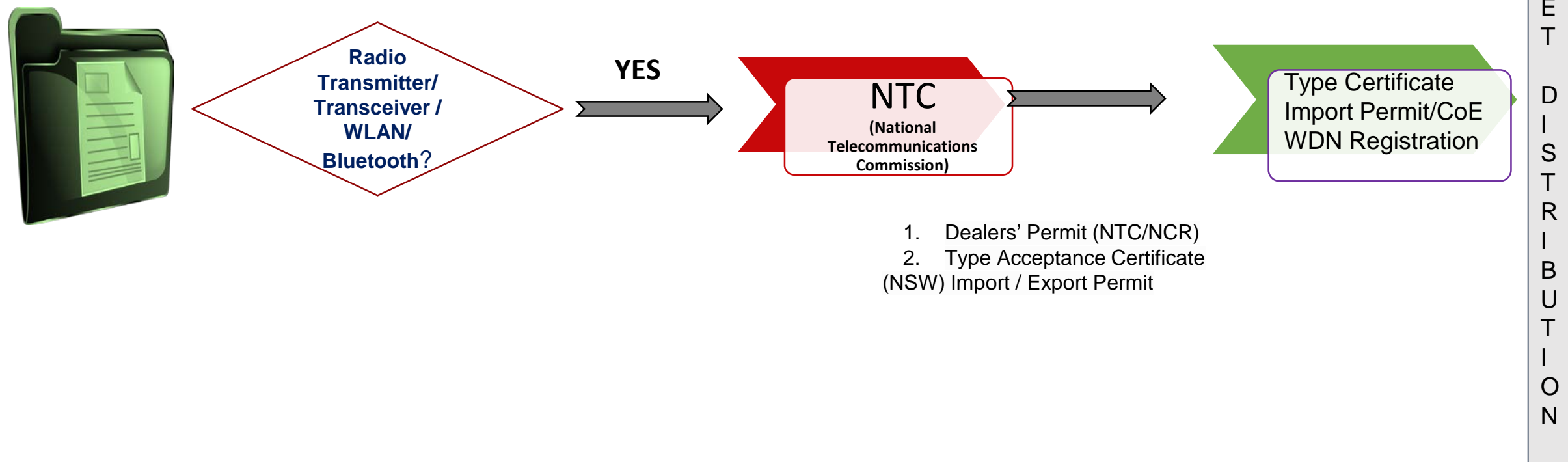
HDD, SSD,
Flash Drive, SD
Card, Tablet,
Laptop, etc.

Magnetic Media

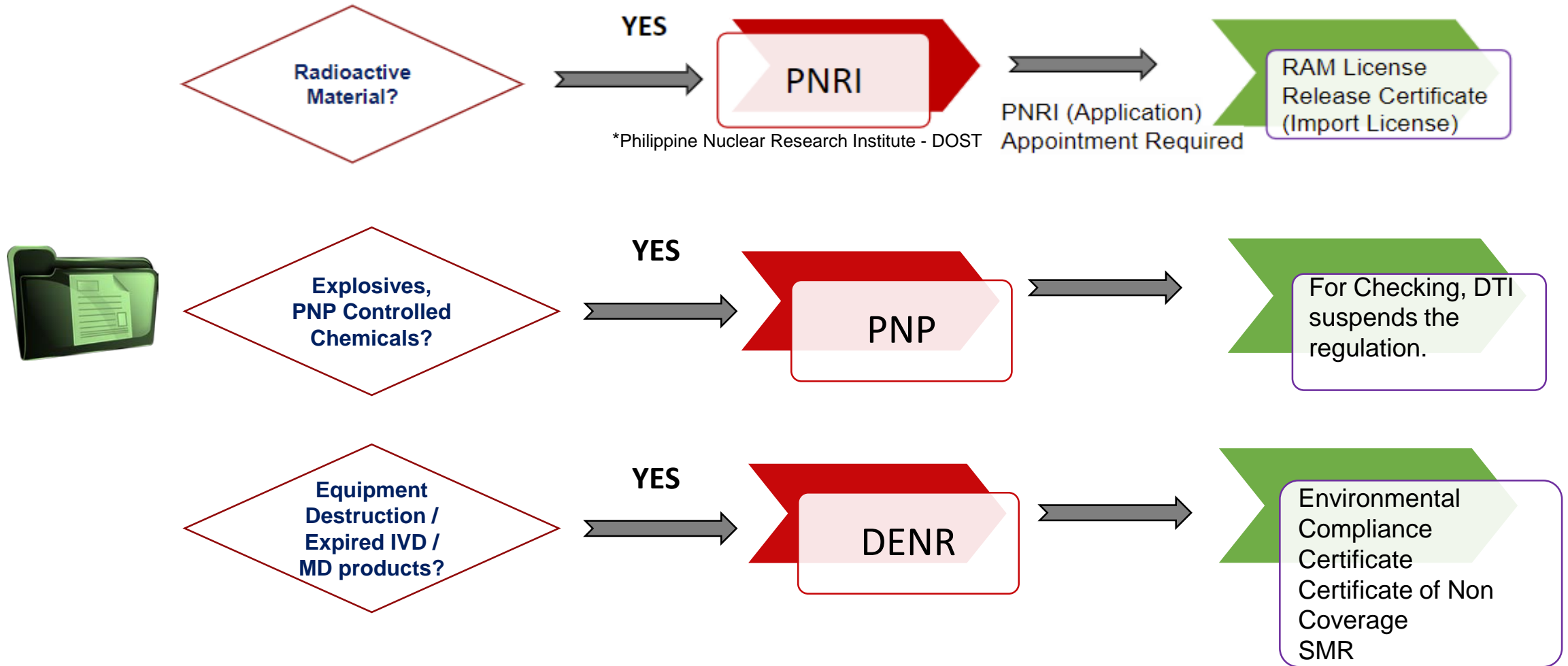


Magnetic tape,
Cassettes,
Video Tape,
Diskettes,
Floppy Discs

PROCESS MAP with other REGULATING AGENCIES



PROCESS MAP with other REGULATING AGENCIES



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*Is this the right way
to In-Vitro Diagnostic
Medical Device
Registration ?*



New Regulatory Requirements for Medical Devices

is based on the

Administrative Order 2018-0002

issued by DOH on 26 January 2018

Guidelines Governing the Issuance of an Authorization for Medical Device based on the ASEAN Harmonized Technical Requirements

**In-Vitro Diagnostic Medical Device
definition based on A.O. 2018-0002:**

*Guidelines Governing the Issuance of
an Authorization for a Medical Device
based on the ASEAN Harmonized
Technical Requirements*



In-Vitro Diagnostic Medical Device — refers to any **reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system** whether used alone or in combination, intended by the manufacturer to be used in-vitro for the examination of specimens, including blood and tissue donation, derived from the human body solely or principally for the purpose of

- a. providing information concerning a physiological or pathological state; or
- b. providing information concerning a congenital abnormality; or
- c. determining the safety and compatibility with potential recipients; or
- d. monitoring therapeutic measures.

DRAFT CIRCULARs



OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD)

I. RATIONALE / BACKGROUND

Republic Act No. 9711 and its Implementing Rules and Regulations, declare that it is the policy of the state to insure the safety, efficacy and quality of health products including IVDs in the country so as to protect the health of the Filipino people.

The signing of the AMDD in 2014, mandated the Philippines to implement the following provisions to a) require the person responsible for placing the IVD in that Member State or the authorized representative to register the IVD with the regulatory authority of that Member State, b) undertake all necessary measures to ensure that only IVD which conform to the AMDD may be placed on markets of that Member State and c) put in place an appropriate system for the registration of IVD with the Regulatory Authority of that Member State.

The Department of Health through the Food and Drug Administration (FDA) - Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopts, issues and implement the AMDD guidelines on the issuance of an authorization for IVD and to provide the regulatory requirements and authorization process.

II. OBJECTIVE

This Administrative Order aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the issuance of an authorization for IVD.

III. SCOPE

This Administrative Order shall cover all IVDs and apply to all manufacturers, traders and distributors (e.g. importers, exporters and wholesalers) of IVD in the Philippines.



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR
No. _____

SUBJECT: Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits

I. RATIONALE

On 25 February 2014, FDA Memorandum Circular No. 2014-005 entitled "Updated List of Medical Devices required to be registered prior to sale, distribution and use" was issued to provide the initial list of medical devices including IVDs that are required for registration with the Food and Drug Administration (FDA).

With the occurrence of the pandemic due to COVID-19, FDA Memorandum (FM) No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" was issued on 12 March 2020 adding COVID-19 test kits to the list of IVDs that require authorization from the FDA prior to their importation, distribution and sale.

FM No. 2020-006 was issued at the outset of the COVID-19 pandemic. Despite the limited clinical data available at that time to support the performance of the products, FM No. 2020-006 was issued requiring only limited documents to facilitate the issuance of Special Certification to provide access to these products and to enable testing of patients suspected to be afflicted with COVID-19.

Considering that developments have been made in establishing clinical data for COVID-19 test kits and there is already adequate supply of these products in the market, it is prudent to require compliance of these products to the FDA technical requirements for product registration similar with other regulated IVDs to ensure their quality, safety and performance. For COVID-19 test kits that have complied to the said technical requirements, it is appropriate to issue a Certificate of Product Registration (CPR) to the said test kit products in lieu of the Special Certification issued under FM 2020-006.

Majority of the above-mentioned IVDs including COVID-19 test kits are required to undergo performance evaluation by the FDA Common Services Laboratory (FDA-CSL) and by the different National Reference Laboratories (NRLs) depending on the respective capacity of said laboratories. These IVDs should pass such performance evaluation prior to the issuance of required authorization by the FDA.

Current List of Registrable In-vitro Diagnostic Medical Device (FDA Memo Circular No. 2014-005)

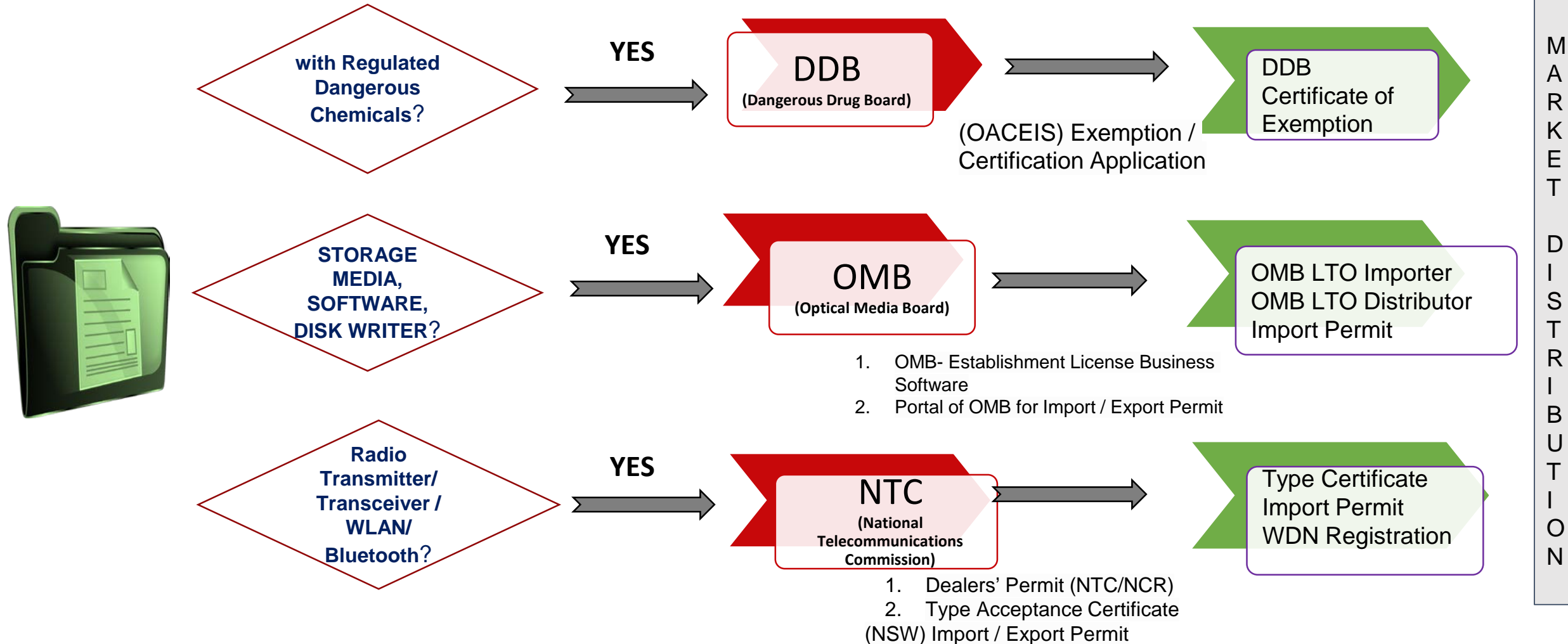
FDA Circular 2020-001:
Blood collection Tube is registrable and
added as IVD medical device

In lieu of the COE, the **LTO of the
establishment** shall be provided as the
point of entry and/or as part of bidding
requirements

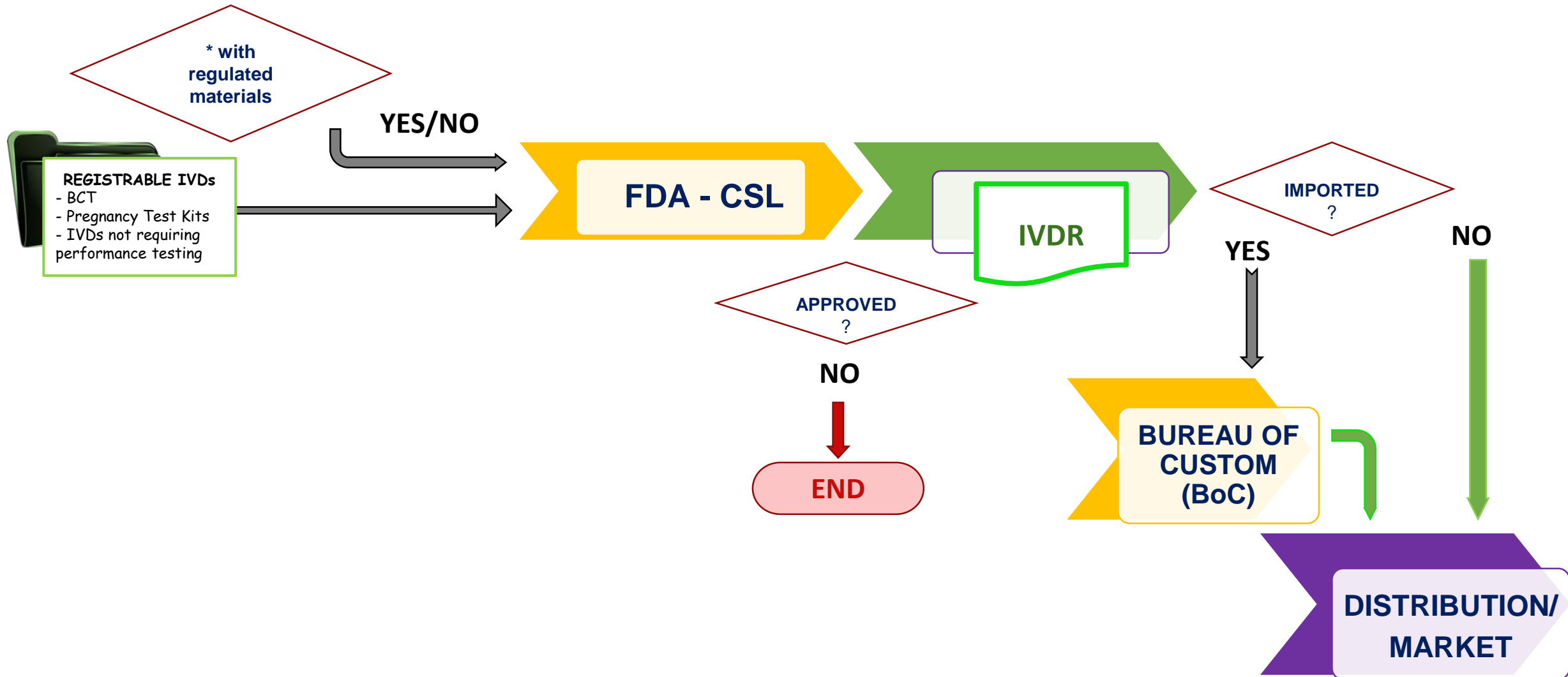
B. In-Vitro Diagnostic (IVD) Medical Devices:

1. **HIV (antibody and/or antigen), HBV (HBsAg and other markers), HCV (antibody and/or antigen) and syphilis (Treponemal and nontreponemal)** kits for:
 - Screening Test
 - Confirmatory Test
 - Other marks for nucleic application systems for in-vitro diagnostic use and test to monitor disease activity (e.g. viral load test, other serologic markers for Hepatitis B)
2. **Single or combination drug screening test kits/reagents** for THC/marijuana, Shabu/MET, Cocaine, Benzodiazepine, Ecstasy/MDMA and Opiates/Morphine
3. **Blood Typing Sera** for Anti-A, Anti-B, Anti-D, Anti-AB
4. **Anti-human Globulin Reagents**
5. **Potentiators** such as enzyme, LISS and albumin
6. **Column Agglutination test** for crossmatching & blood typing
7. **Pregnancy test kits/reagents**
8. **Leptospirosis test kits/reagents**

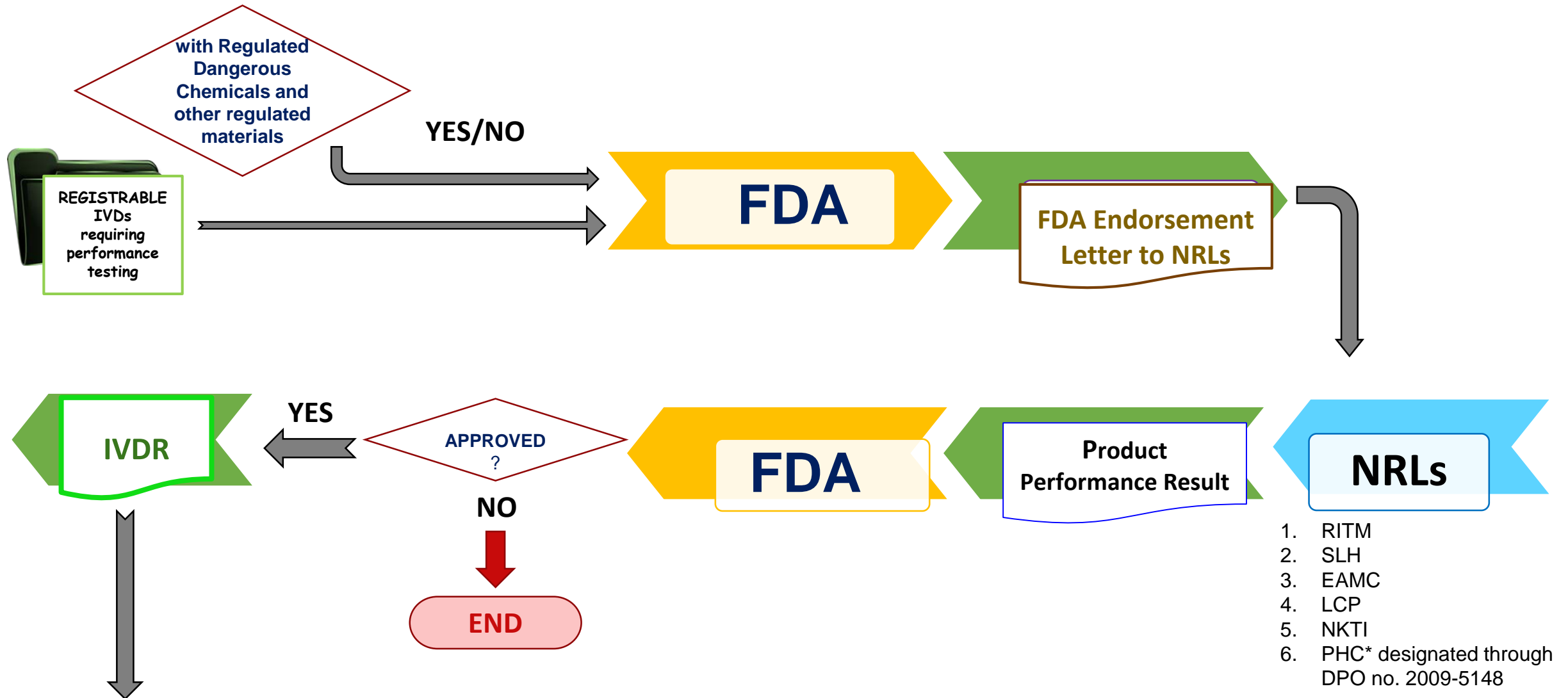
PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT

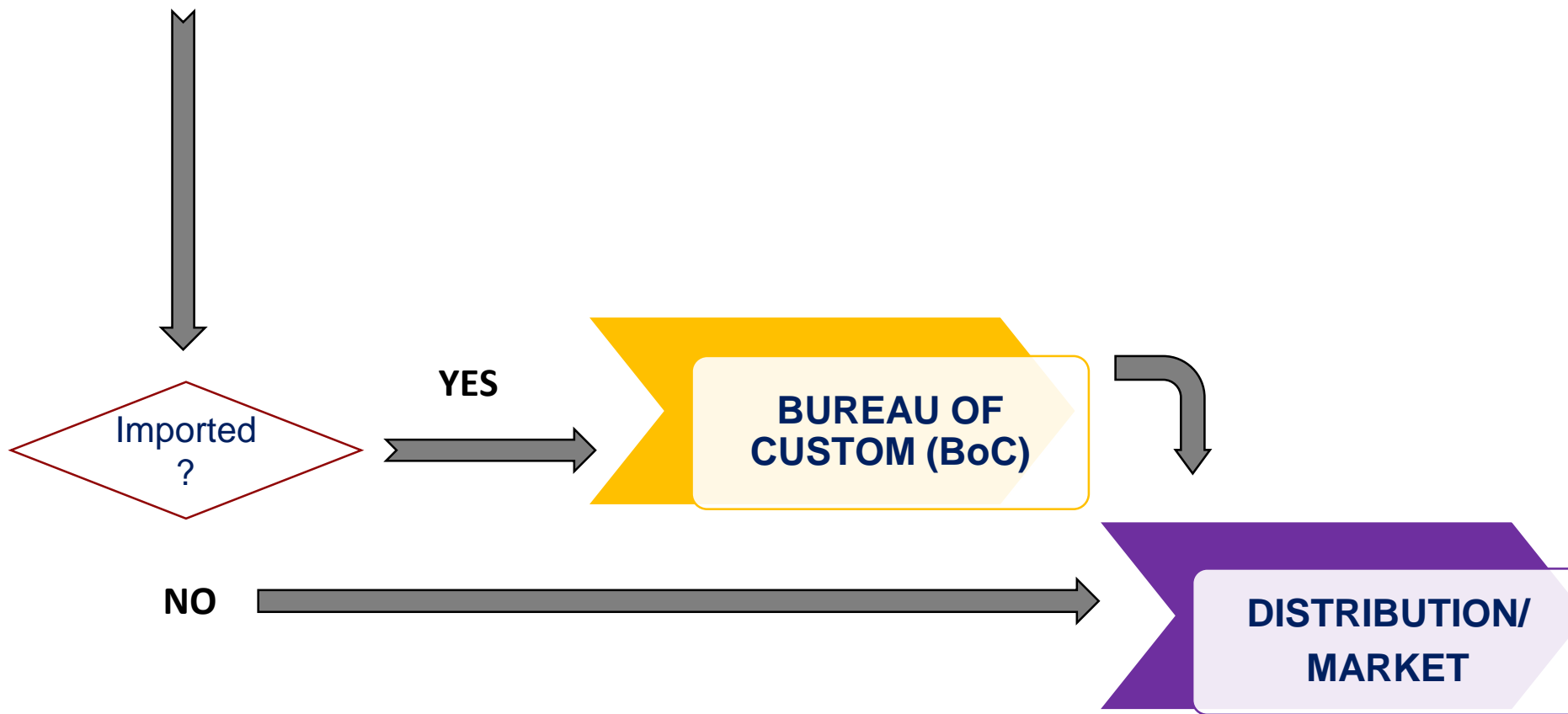


PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT



PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT





PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT

NATIONAL REFERENCE LABORATORIES (NRLs)

East Avenue Medical Center:

1. NRL for Environmental & Occupational Health
2. NRL for Toxicology
3. NRL for Micronutrient Assay
4. NRL for Industrial and Chemical Emergencies

****Single or combination drug screening test kits/reagents**

National Kidney and Transplant Institute:

1. NRL for **Hematology**
2. NRL for **Immunohematology**
3. NRL for Urinalysis
4. NRL for Anatomic Pathology for Renal Diseases and other Unassigned Organ Systems
5. NRL for **Cellular-Based Product Testing**

AO No. 2013-0012 "Rules and Regulations Governing Accreditation of Health Facilities Engaging in Human Stem Cell and Cell Based or Cellular Therapies in the Philippines"

Lung Center of Philippines (LCP):

1. NRL for General Clinical Chemistry
2. NRL for Anatomic Pathology for Pulmonary and Pleural Diseases

San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SLH-SACCL):

1. NRL for **HIV/AIDS**
2. NRL for **Hepatitis B and Hepatitis C**
3. NRL for **Syphilis and Other Sexually-Transmitted Infections**

Philippine Heart Center:

1. National Reference Laboratory for Anatomic Pathology for Cardiac Diseases
2. National Reference Laboratory for Cardiac Markers

Research Institute for Tropical Medicine (RITM):

1. NRL for Antimicrobial Resistance
2. National Tuberculosis Reference Laboratory
3. NRL for Transfusion-Transmissible Infections
4. NRL for Dengue and Other Arboviruses*
5. NRL for Influenza and Other Respiratory Viruses*
6. NRL for Emerging and Re-Emerging Bacterial Diseases*
7. NRL for **Leptospirosis***
8. NRL for Special Pathogens*
9. NRL for Mosquito Vectors of Human Diseases*
10. NRL for Malaria and Other Parasites*
11. NRL for Schistosomiasis*
12. NRL for Rabies and other Lyssaviruses**
13. NRL for Polio and other Enteroviruses
14. NRL for Measles and other Exanthems
15. NRL for Invasive Bacterial Vaccine Preventable Diseases
16. NRL for Rotavirus and other Enteric Viruses***

AO No. 2015-0050 "Designation of RITM as the National Reference Laboratory for Rotavirus and other Enteric Viruses"

1. NRL for Bacterial Enteric Diseases**
2. NRL for Mycology
- **COVID-19 TEST KITS**

* These NRLs shall support the Emerging and Re-emerging Infectious Disease Control Program

** These NRLs shall support the Neglected Tropical Disease Control Program

***These NRLs shall support the Food and Waterborne Disease Control Program

IVD Medical Device Application Process

IVD Devices/REAGENTS			
Timeline: 90 working days Based on Citizen Charter	Fees to be Paid Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing	Initial Filing : Email & Share Google Link Drive	Performance Evaluation Fees and Timeline varies per NRLs
24 working days Based on Citizen Charter	Php5,000.00 + 1% LRF for renewal with 5 years validity	Renewal Filing : Email & Share Google Link Drive	Performance Evaluation Fees and Timeline varies per NRLs

In Summary

“What are the latest updates on medical device registration?”

“Are there any other regulatory agencies that I have to know about?”

“What are the regulatory processes that I have to know prior to medical device distribution / market availability?”

KEY TAKE AWAYS :

1. Be knowledgeable about your products
 2. Conduct a detailed product assessment
 3. Identify the regulatory body/agencies that regulate your products other than FDA
-
1. Expand your medical device knowledge; attend to various trainings
-
1. Join and participate in PAMDRAP committees

References:

1. DEPARTMENT ORDER: No. 2020-0820- Institutionalizing and Strengthening the National Reference Laboratories in the Philippines
Link: <https://www.fda.gov.ph/departments-order-no-2020-0820-institutionalizing-and-strengthening-the-national-reference-laboratories-in-the-philippines/>
1. DDB Certification and Exemption
Link: <https://www.ddb.gov.ph/legal-services/certification-and-exemption>
1. Rules and Regulations implementing RA No. 9239 known as the “Optical Media Act of 2003” -
Link: <https://www.omb.gov.ph/wp-content/uploads/Implementing-Rules-and-Regulations-.pdf>
1. FDA Citizen Charter - CDRRHR
Link: https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Citizen_s-Charter-CDRRHR_CPR_-31-March-2022.pdf

A scenic landscape featuring rolling hills under a hazy, golden sky. In the foreground, a two-lane asphalt road with a double yellow center line stretches towards the horizon. The hills are covered in green vegetation, with some areas appearing to be cleared or harvested, showing a lighter brownish-yellow color. The overall atmosphere is warm and serene.

A good plan is like a road map:
it shows the final destination and usually the
best way to get there.

H. Stanley Judd

THANK YOU FOR LISTENING !