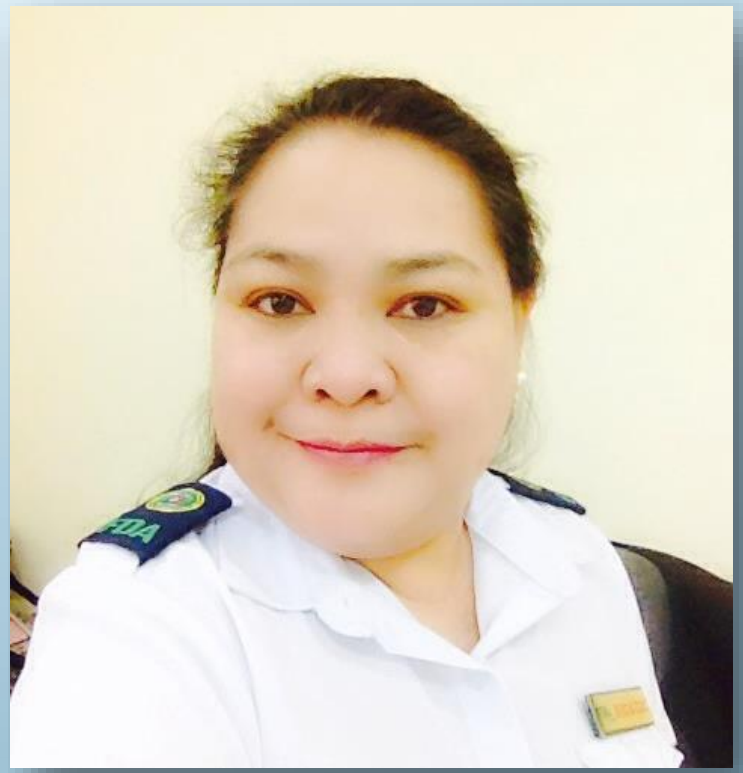
# MARIA CECILIA C. MATIENZO



Division Chief of the Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research.

A graduate of Bachelor of Science in Electronics and Communications Engineering and Master of Arts in Major in Public Administration

Have been in the Department of Health for 27 years, 12 years spent doing Hospital Equipment Management at the Hospital Maintenance Service and 15 years with Medical Device Regulation.

# Updates on Philippine Regulatory System

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# ASIAN HARMONIZATION WORKING PARTY

## What is happening now?

Product Registration

- Initial application
- Automatic renewal of MDs and regular renewal for IVDs
- Performance Testing for IVDs
- Amendments
- Certificate of Exemption (COE) for non-registrable devices
- Certificate of Non-radiation CNR)
- New List of Registrable product
- Existing Fees

Establishment License

Distributors/importers:

- Unified licensing
- e-LTO
- Post-market inspection (PLI)

## What's in can?

- Final Draft of the new regulatory requirements that will consist the new classification of medical devices
- Classification rule guide
- Abolition of CNR to be replaced by either notification or Listing
- Pilot testing of the new regulatory guidelines
- Implementation of Class A notification
- **Increase in fees**

## Looking forward to AMDD implementation

- Full registration by classification
- COE will just apply for all exempted medical devices that are not required to be registered like donation in bulk, for research and education purposes, etc.
- Required standards will be released
- Different guidance documents for labeling, classification, etc. to support the new regulatory guidelines
- new processing timelines based on classification
- Computerization/on-line

# Salamat Po!