

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

September 8, 2014

DEPARTMENT MEMORANDUM No. 2009- 0086-B

TO: BUREAU DIRECT

BUREAU DIRECTORS, REGIONAL DIRECTORS, HEAD OF NRLs, HOSPITAL CHIEFS, HEAD OF LABORATORIES, REGULATORY OFFICERS AND OTHER CONCERNED OFFICIALS

SUBJECT: AMENDMENT TO DEPARTMENT MEMORANDUM NO. 2009-0086- A ENTITLED, "IMPLEMENTATION OF EXTERNAL QUALITY ASSESSMENT PROGRAM AS REGULATORY REQUIREMENT FOR LICENSING OF CLINICAL LABORATORIES"

Pursuant to Administrative Order No. 2007-0027 entitled "Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines," Section VI.B.1.f.ii.states that, "The clinical laboratory shall participate in an EQAP administered by designated NRL or other local and international EQAP approved by the DOH." Hence, Certificate of Participation on EQAP is required for the renewal of the license to operate of clinical laboratories in the BHES and respective Regional Offices.

- I. The guidelines stated below shall be imposed as one of the requirements:
 - A NEQAS Certificate of Participation/ Proficiency Testing of previous year shall be considered for all clinical laboratories performing the following services:
 - Hematology for all categories of Clinical Laboratories issued by National Kidney & Transplant Institute (NKTI)
 - HIV, HBV, HCV, Syphilis and other STIs for clinical laboratories performing such services issued by STD-AIDS Cooperative Central Laboratory (SACCL), San Lazaro Hospital (SLH)
 - c. Drug and Drinking Water issued by East Avenue Medical Center (EAMC)
 - d. Clinical Chemistry for all clinical laboratories offering Chemistry services issued by Lung Center of the Philippines (LCP)
 - e. Parasitology for all categories and all clinical laboratories offering AFB microscopy service; Bacteriology for all tertiary clinical laboratories and TB Culture & Sensitivity for capable tertiary clinical laboratories by Research Institute for Tropical Medicine (RITM)

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J Elliott

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Table of Contents Science Department Memo

- 1. Understanding the eBook Science Department Memo
 - The Rise of Digital Reading Science Department Memo
 - Advantages of eBooks Over Traditional Books
- 2. Identifying Science Department Memo
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
- 3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - $\circ\,$ Features to Look for in an Science Department Memo
 - User-Friendly Interface
- 4. Exploring eBook Recommendations from Science Department Memo
 - Personalized Recommendations
 - Science Department Memo User Reviews and Ratings
 - Science Department Memo and Bestseller Lists
- 5. Accessing Science Department Memo Free and Paid eBooks

- Science Department Memo Public Domain eBooks
- Science Department Memo eBook Subscription Services
- Science Department Memo Budget-Friendly Options
- 6. Navigating Science Department Memo eBook Formats
 - ∘ ePub, PDF, MOBI, and More
 - Science Department Memo Compatibility with Devices
 - Science Department Memo Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - o Adjustable Fonts and Text Sizes of Science Department Memo
 - Highlighting and Note-Taking Science Department Memo
 - o Interactive Elements Science Department Memo
- 8. Staying Engaged with Science Department Memo
 - o Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Science Department Memo
- 9. Balancing eBooks and Physical Books Science Department Memo
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Science Department Memo
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Science Department Memo
 - Setting Reading Goals Science Department Memo
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Science Department Memo
 - Fact-Checking eBook Content of Science Department Memo
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development

- Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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Validation of Cleaning Processes (7/93) Aug 26, 2014 — Examine the detail and specificity of the procedure for the (cleaning) process being validated, and the amount of documentation required. We ... PDA Technical Report No. 29, Revised 2012 (TR 29) ... 49, Points to Consider for Biotechnology Cleaning Validation. It presents updated information that is aligned with lifecycle approaches to validation and ... Guidance on aspects of cleaning validation in active ... The PDA Technical Report No. 29 - Points to Consider for Cleaning Validation 4 is also recommended as a valuable guidance document from industry. The following ... Annex 2 Visually clean is an important criterion in cleaning validation. It should be one of the acceptance criteria used on a routine basis. Personnel responsible for ... Points to Consider for Biotechnology Cleaning Validation 49, Points to Consider for Biotechnology Cleaning Validation aligns cleaning validation practices with the life cycle approaches to validation, as enabled by ... What is Cleaning Validation in the Pharmaceutical Industry? Cleaning validation is a process used in the pharmaceutical, biotech, and medical device industries to provide documented evidence that equipment and facilities ... draft working document for comments Sep 21, 2020 — Aspects of cleaning validation and cleaning verification should be considered in quality metrics, with. 471 performance indicators identified ... Cleaning Validation Guidelines - A Complete List 2022 [May 2020] Points to consider on the different approaches -including HBEL - to establish carryover limits in cleaning validation for identification of ... Technical Report No. 49 Points to Consider for ... by TF Contributors — Cleaning validation plays an important role in reducing the possibility of product contamination from biopharmaceutical manufacturing equipment. It demonstrates ... Cleaning Validation: Protocol & Guidelines Cleaning validation is a procedure

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