

THE IMPLEMENTATION AND ITS EFFECT OF ISO 15189 RECOMMENDATIONS ON
CLINICAL CHEMISTRY LABORATORY OF HOSPITAL FOR TROPICAL DISEASES

VIMON YANPANICH 5237695 SILS/M

M.Sc. (CLINICAL LABORATORY SCIENCE)

THESIS ADVISORY COMMITTEE : NISARAT OPARTKIATTIKUL, M.D., Ph.D.,
WANIDA WONGTIRAPORN, M.D., M.Sc., PANUTSAYA TIENTADAKUL, M.D.,
PREECHAYA WONGKRAJANG, M.D.

ABSTRACT

The researcher implemented and monitored ISO 15189 recommendations in the Clinical Chemistry Laboratory, the Hospital for Tropical Diseases and observed the changes by quality indicators. Evaluation of ISO 15189 requirements to determine priority of the area of development was performed and six quantitative key performance indicators (KPIs) were established accordingly. Qualitative KPI were measured by using a self-assessment checklist was also performed. After six months of ISO 15189 implementation, five KPIs which were calibration rate of laboratory equipment, critical value reporting rate, average customer satisfaction rate, external quality assessment (EQA) passing rate and the passing rate of staff competency assessment were increased, while specimen rejection rate was decreased and all 243 requirements were complied. Moreover, all laboratory staff gained clear knowledge and more understanding in quality management system. Their 'quality conscious' was priceless and was expressed from the sustainability of the quality system and continuous improvement. The key success factors were strong determination of the researcher, good team working and financial support from top management.

KEY WORDS: ISO 15189 / QUALITY INDICATOR / IMPLEMENTATION

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