

Updating the Thai NIH Quality Management Checklist to Conform with ISO 35001



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Abstract

- This presentation outlines a Biorisk Management (BRM) partnership project that involved the development of an updated audit checklist to use for the assessment of lab safety conformity with ISO 35001 and ISO 15190, the Thailand Pathogens and Animal Toxins act, and the WHO LBM 4th edition, that incorporated key biorisk management and related program elements.
- The new audit checklist was used as a tool to assess the BRM program in 22 different laboratories at the Thailand NIH to identify gaps and needs for priority list of next steps.

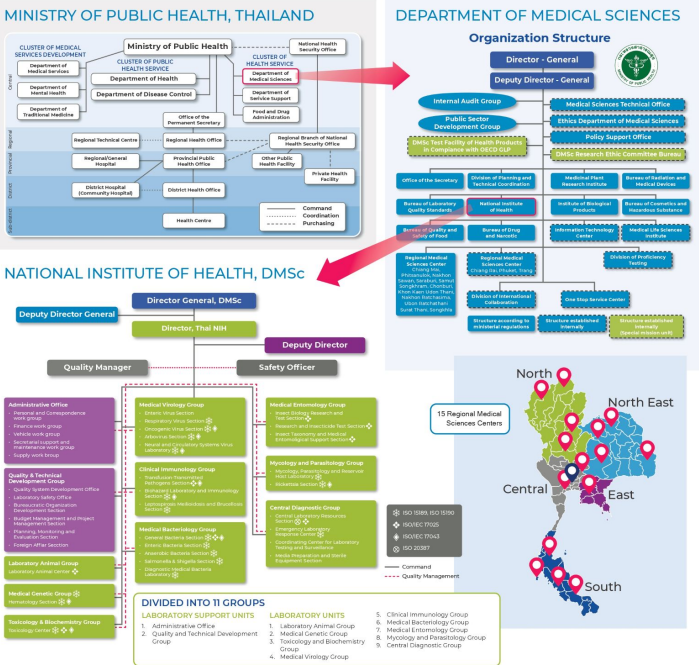
ISO 35001: 2019

BIORISK MANAGEMENT FOR LABORATORIES AND OTHER RELATED ORGANIZATIONS

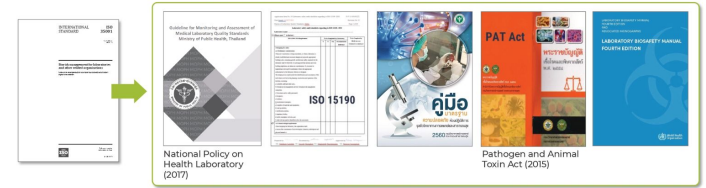
- This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials.
- This document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials.
- This document is intended to complement existing International Standards for laboratories.

Background and Introduction

- The presentation will provide an overview of the findings identified from the 22 inspections, and will also note the recommendations for future actions to address the gaps and deficiencies identified.
- This new twinning initiative is a unique, first of its kind pairing and networking project opportunity pairing Biorisk Management (BRM) experts from sister Australian laboratories with BRM professionals from Thailand and Malaysia. Projects that support BRM in Thailand and Malaysia, will also ultimately support the Regional Public Health Laboratory network and all 14 member countries.



Project Goal: To incorporate ISO 35001 into Existing Thai NIH Practices



Biorisk Management is Critical

INCORPORATING ISO 35001 ENHANCES:

- Lab Safety
- Compliance
- Public Health Security
- Environmental Protection

Project Objectives

- Form a committee comprising Safety and Quality Management representatives
- Review existing policies and SOPs
- Develop an audit checklist ensuring conformity with ISO 35001
- Distribute checklist and request completion
- Analyze data to identify strengths and safety gaps
- Prepare a report for the NIH Director

Establishment of the Committee



Review of Existing Policies



Development of Updated Quality Management Audit Checklist

English Version	Thai Version
<p>4.3.2 Risk assessment and security program The organization shall ensure that suitable methodologies for assessing and prioritizing biorisks are identified, implemented, maintained, and documented (ISO 35001: 6.1.2)</p> <p>7.3 Biological safety cabinets a) Biosafety cabinet certification of biosafety cabinets must be based on quality indicators according to the manufacturer's standards, e.g. 1) Downflow velocity test 2) Inflow velocity test 3) HEPA filter leak test 4) Smoke patterns test 5) Site installation test (NIH Safety Manual)</p> <p>16 Transport of samples and hazardous materials Transport security: The organization shall establish plans to address safety and security incidents that might occur during internal and external transport. The organization shall address all applicable international, national and local transportation requirements and ensure that a system is in place to regulate packaging, labelling, marking and documentation of infectious substances to minimize the likelihood of exposure and/or release during transport. (ISO 35001)</p>	<p>4.3.2 ให้องค์กรประเมินและจัดลำดับความเสี่ยงทางชีวภาพและอันตรายจากสารพิษตามระดับความเสี่ยงที่ระบุและจัดลำดับความเสี่ยง (ISO 35001: 6.1.2)</p> <p>7.3 ตู้ชีวปลอดภัย</p> <p>ก) การหาใบรับรองตู้ชีวปลอดภัยของตู้ชีวปลอดภัยต้องอิงตามตัวชี้วัดคุณภาพตามมาตรฐานของผู้ผลิต (NIH Safety Manual)</p> <p>1. Downflow velocity test 2. Inflow velocity test 3. HEPA filter leak test 4. Smoke patterns test 5. Site installation test (NIH Safety Manual)</p> <p>16 การขนส่งสิ่งมีชีวิตอันตราย และของอันตรายทางชีวภาพและการขนส่งสารพิษระหว่างสถานที่และระหว่างการขนส่งภายในประเทศและระหว่างประเทศ</p> <p>16. การขนส่งสิ่งมีชีวิตอันตราย และของอันตรายทางชีวภาพและการขนส่งสารพิษระหว่างสถานที่และระหว่างการขนส่งภายในประเทศและระหว่างประเทศ</p> <p>16. การขนส่งสิ่งมีชีวิตอันตราย และของอันตรายทางชีวภาพและการขนส่งสารพิษระหว่างสถานที่และระหว่างการขนส่งภายในประเทศและระหว่างประเทศ</p> <p>(ISO 35001)</p>

16 Sections with over 500 Questions

Sections
Designing for safety
Safety management program
Hazard identification and risk assessment
Biosafety and biosecurity hazards
Chemical hazards
Physical hazards
Emergency preparedness and response
Fire safety
Laboratory ergonomics
Equipment safety
Safe personnel work practices
Personal protective equipment
Transport of samples and hazardous materials
Waste disposal
Housekeeping practices
Incidents, injury, accidents, occupational illnesses, and nonconformity for corrective action

Distribute Checklist for Internal Audit



Results

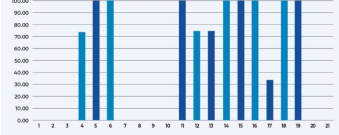
ANALYSIS OF DATA TO IDENTIFY STRENGTHS AND SAFETY GAPS

Section	Average Score
Waste disposal	92.36
Safety management program	90.84
Housekeeping practices	87.41
Designing for safety	82.13
Personal protective equipment	75.47
Emergency preparedness and response	75.31
Biosafety and biosecurity hazards	73.42
Safe personnel work practices	71.77
Hazard identification and risk assessment	66.44
Incidents, injury, accidents, occupational illnesses, and nonconformity for corrective action	63.27
Equipment safety	61.23
Fire safety	59.85
Chemical hazards	58.99
Laboratory ergonomics	55.86
Transport of samples and hazardous materials	50.40
Physical hazards	50.17

SAFETY MANAGEMENT IS OUR STRENGTH



TRANSPORT OF SAMPLES AND HAZARDOUS MATERIALS



TRANSPORT IS AN AREA FOR IMPROVEMENT



Project Title: Updating the Thai NIH Quality Management Checklist to Conform with ISO 35001

Updating the Thai NIH Quality Management Checklist to Conform with ISO 35001

Overview:

This presentation outlines a Biorisk Management (BRM) partnership project that involved developing uniformity with the hazardous waste management policies at the NIH Thailand, as biomedical and hazardous waste management are a critical component of the biorisk management plan at the institution. The project reviewed existing policies with related local, national and international waste management best practices to update our own biomedical waste programs. Waste checklists, updated standard operating procedures, disposal forms, and training materials were created as part of the project. The tools and checklists were utilized in 22 labs at the NIH and the results were used to identify the hazardous waste programs. The updated and standardized biosecurity and hazardous waste policies will be used within all 13 labs within the NIH Thailand and then shared with all 14 member laboratories that are located within the Ministry of Public Health, Thailand. This new twinning initiative is a unique, first of its kind pairing and networking project opportunity pairing Biorisk Management (BRM) experts from sister Australian laboratories with BRM professionals from Thailand and Malaysia. Projects that support BRM in Thailand and Malaysia, will also ultimately support the Regional Public Health Laboratory network and all 14 member countries.

Conclusions

- Utilized updated ISO 35001 audit checklist to identify:
 - BRM strengths
 - Weaknesses, gaps, areas for improvement
 - Plan targeted training and retraining

Lessons Learned

- Labs are concerned about failing
- We need to provide assurance without fear of penalty
- Important for labs to be aware of all areas on checklist
- Quality and biorisk systems are not equal

Acknowledgements

- NIH, DMS Staff, Safety Officer, Director
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