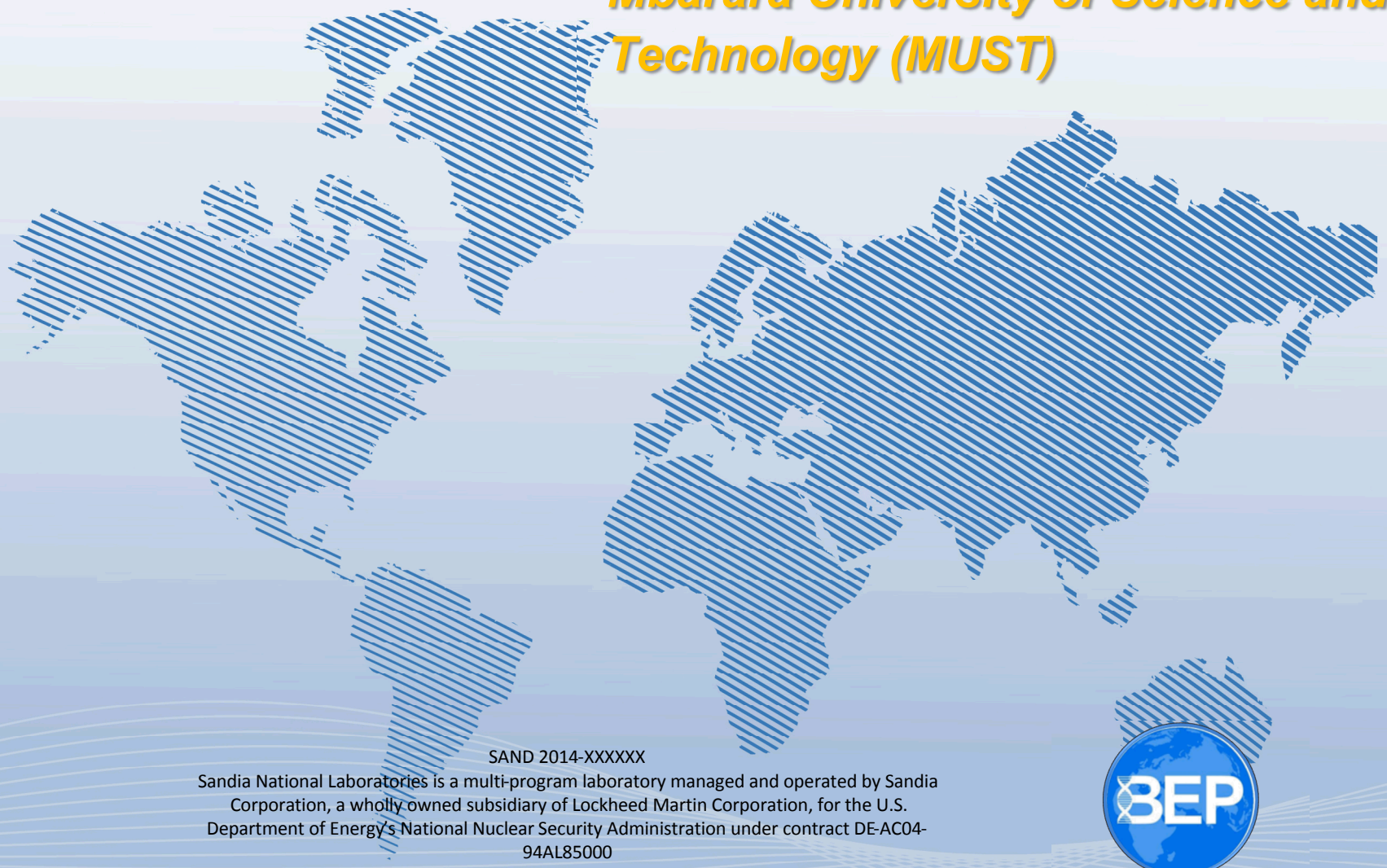
Workshop on Introduction to Biorisk Management and Biorisk Management Curriculum Development

SAND2014-4145P

June 2014

Mbarara University of Science and Technology (MUST)



SAND 2014-XXXXXX
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BEP

Outline

- Introductions
- Pre-Workshop Assessment
- Teaching models and approaches, the Global Biorisk Management Curriculum (GBRMC)
- Orientation to Biorisk Management
- Identifying audience, context, learning objectives
- Curriculum design

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Roundtable Introductions

- Your name?
- Your position?
- Your Department, Role?

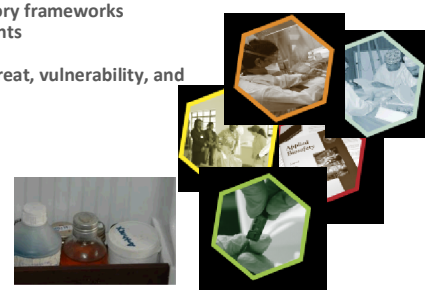
International Biological Threat Reduction

Innovative solutions for countering biological threats globally

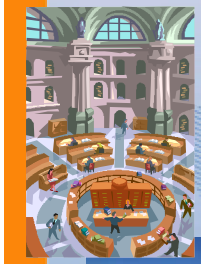
- Promote the responsible use of biological agents, equipment, and expertise globally.
- Strengthen capacities to safely, securely, and responsibly detect, handle, and control dangerous biological agents.
- Improve understanding and management of the risks associated with accidental and deliberate misuse of biological agents.

IBTR Core Capabilities

- **Laboratory biorisk management**
  - Biorisk management standards and regulatory frameworks
  - Core biorisk management program documents
  - Lab design / programming expertise
  - Facility specific biosafety and biosecurity threat, vulnerability, and assessments
  - Biorisk (biosafety and biosecurity) upgrades
- **Biothreat identification and analysis**
  - Global analysis
  - Country and regional analyses
- **Capacity building and outreach**
  - Biorisk management training
  - Training centers
  - Law enforcement
- **Building inherently safer and more secure biomedical capabilities**
  - Surveillance and control
  - Public and vet health
  - Incident detection and response



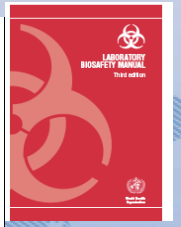
Example: Building Human Capacity to Address Biorisks

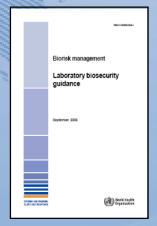


- **Global Biorisk Management Curriculum**
  - Develop and maintain a customizable library of courses designed based on international best practices in biorisk management and sustainable training techniques
    - *Catalog: http://biosecurity.sandia.gov/gbrmc/catalog.html*
  - Network of trainers to provide document and quality control and to offer a platform for shared experiences and problem solving
- **Conduct training for different stakeholders**
  - Policy makers, lab workers, biosafety/biosecurity officers, lab directors, law enforcement
  - Topics include: biorisk management, molecular diagnostics, infectious substance shipping, and biothreat identification and response
  - Training platforms include: classroom, distance-learning, lab, tabletop exercises, and full-scale field exercises
- **Development of regional training centers**
  - Physical training centers and regional consortia
  - Train-the-Trainer programs
- **Support to international organizations' human capacity efforts, including WHO, OIE, and INTERPOL**

Terminology and Definitions

- Biosafety: The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins or their accidental release' (WHO, 2004)
- Biosecurity: Protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion, or intentional release of biological agents and toxins and related resources, as well as unauthorized access to, retention, or transfer of such material' (WHO, 2006)[2]





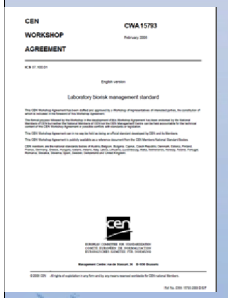
- [1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)
- [2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

Definitions, continued

- The practices of **biosafety and biosecurity** are combined into an **integrated effo t** known as **biorisk management** where the goals are, concurrently, to work safely and to keep the work secure.

  Biorisk management (BRM) can be further defined as the actions taken (by laboratories or facilities which handle, store, or dispose biological agents or toxins) to control or minimize biorisk to acceptable levels in relation to employees, the community and others, as well as the environment, which could be directly or indirectly exposed to biological agents or toxins (adapted from CWA 15793:2011[1]).

[1]Laboratory biorisk management standard (CWA 15793:2011)



Definitions, continued

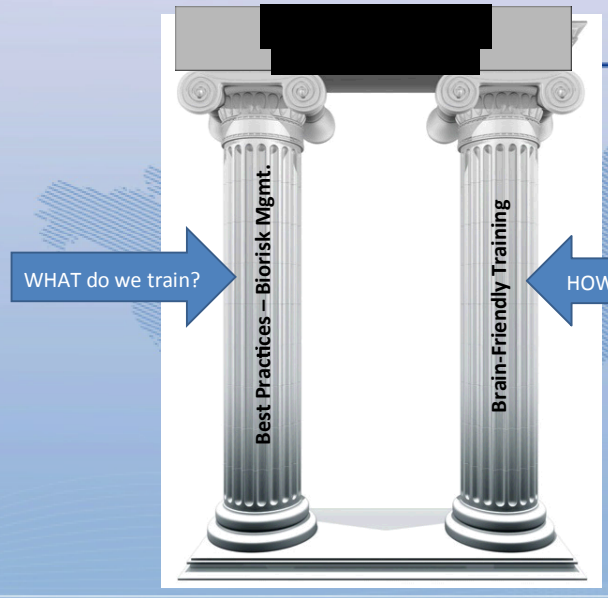
- "Dual Use" are legitimate goods and technologies that have the potential to be misappropriated and misused to cause harm
  - Dual Use Research of Concern: "Research that…can be **reasonably anticipated** to provide knowledge, products, or technologies that could be ***directly*** misapplied by others to **pose a threat** to public health and safety, agricultural crops and other plants, animals, the environment, or material" [National Science Advisory Board on Biosecurity]

GBRMC

GBRMC = Global Biorisk Management Curriculum

Mission

- Biosafety & Biosecurity training materials. . .
  - Strategic
  - Sustainable
  - Anywhere, anytime
  - Well-branded
  - Well-managed



Biorisk Management Resources

- CWA 15793:2011 – Laboratory biorisk management standard (+ CWA 16393 guidance)
- CWA 16335 - BioSafety Professional (BSP) Competences
- World Health Organization Laboratory Biosafety Manual
- World Health Organization Laboratory Biosecurity Manual
- OECD Best Practice Guidelines for Biological Resource Centres
- Guidelines for Biosafety Laboratory Competency (*MMWR* Supplement Vol. 60)
- NSABB Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information
- Biological and Toxin Weapons Convention
- Local guidelines & regulations
- Current best practices
  - example: U.S. Biosafety in Microbiological and Biomedical Laboratories

Global Biorisk Curriculum Library, 1

Basic Track

Audience: all personnel involved in biorisk management

- Biorisk Management Basics
  - Orientation to biorisk management
  - Bioethics
  - Introduction to Dual Use Research of Concern
  - Biorisk Characterization & Evaluation
  - Biosafety Risk Assessment
  - Biosecurity Risk Assessment
  - Biorisk Mitigation Strategies
  - Introduction to Incident Management & Response

Laboratory-Level Track

Audience: Biorisk Management Advisors, Scientific/ Laboratory Management, Lab Workforce

- Lab-Level Administrative Controls
  - Human Performance for Biorisk Management in the Laboratory
  - Developing, Evaluating, Validating, and Communicating Standard Operating Procedures
  - Hazard & Risk Communication in the Laboratory

Laboratory-Level Track, continued

- Lab-Level Operational Controls
  - Biocontainment Facility Features
  - Engineering Controls and Laboratory Equipment
  - Good Laboratory Work Practices
  - Personal Protective Equipment
  - Decontamination
  - Biological Waste Disposal
  - Laboratory Biosecurity
  - Field Biosecurity
  - Shipping Infectious Substances and Biological Specimens
- Reporting, monitoring, and Response
  - Incident Recognition and Response in the Laboratory

Global Biorisk Curriculum Library, 2

Management & Leadership Track

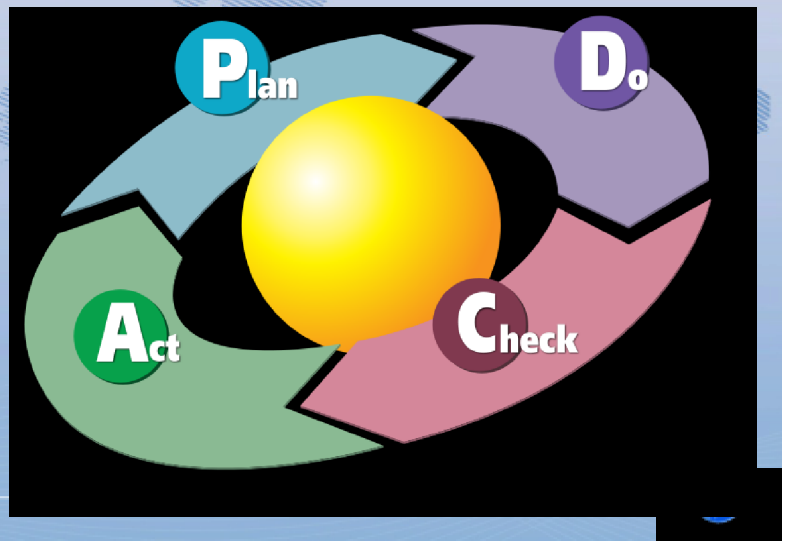
Audience: (Policy Makers) Top Management, Biorisk Management Advisors, Scientific/Laboratory Management

- Policy, Planning, and Assessment
  - Writing and Communicating Biorisk Management Policy
  - Considerations for Training in Biorisk Management
  - Developing, Conducting, and Maintaining a Hazard Inventory
  - Identifying Legal Requirements that Impact BRM
  - Establishing Work Program Review & Approval
  - Establishing and Communicating Biorisk Management Goals, Objectives, Roles, and Responsibilities
- Developing and Maintaining Human Capacity for Biorisk Management (Managing People)
  - Managing Human Performance in the BRM Workforce
  - Establishing and Maintaining Formal and Informal BRM Mentoring Programs
  - Establishing and Maintaining Worker Health Programs
  - Developing and Maintaining Roles & Responsibilities for Risk-based Access to, Control of, and Accountability for Biological Agents and Toxins.

Management & Leadership Track, continued

- Developing and Maintaining Physical Infrastructure for Biorisk Management
  - Understanding & Maintaining Facilities & Equipment for Biorisk Management
  - Basic Features & Maintenance for Physical and Information Security Measures
- Incident Management & Response
  - Incident Response Planning and Preparation
  - Incident Response & Investigation
  - Incident Response Evaluation & Improvement
- Measuring and Improving Biorisk Management Performance
  - Measurement and Analysis of Biorisk Management System Performance
  - Conducting Audits and Inspections to Assess Biorisk Management Performance
  - Revising and Improving a Biorisk Management System based on Performance Results
  - Establishing and Using Performance Indicators

Biorisk Management – Continuous Improvement



Biorisk Management: AMP Model *(World Health Organization)*

Biorisk Management =
Assessment, Mitigation, Performance

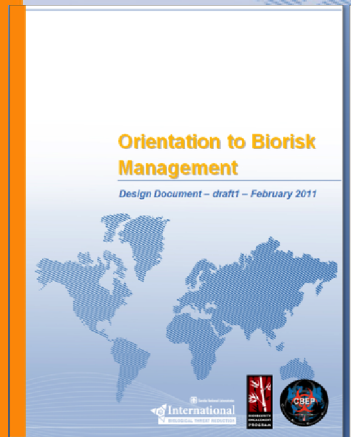
Assessment	Mitigation	Performance
Hazard ID Risk Assessment	Biorisk Control Measures Risk Management	Metrics Indicators Review/Revision

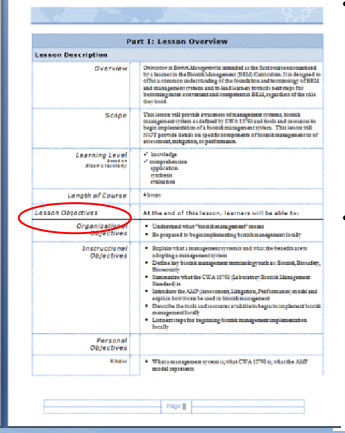
GBRMC Course Components

- Design Document
  - Course objectives, pre-requisites (for students & trainers), course outline, etc.
- Instructor's Guide
  - Detailed notes
  - Instructions and materials for interactive exercises
  - Handouts, if used
- Slide Deck

- Student Guide
  - Student workbook
  - References & resources
- Instructor and Student Evaluation materials
- References & resources
- Other materials as needed

GBRMC Components: Design Document (DD)

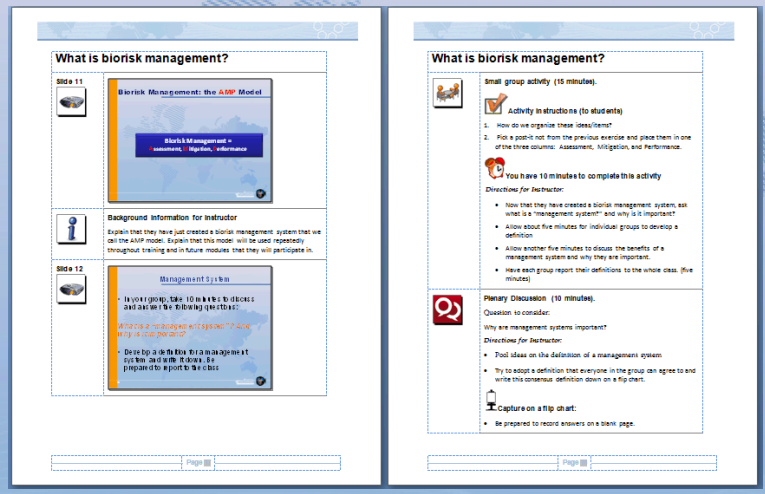




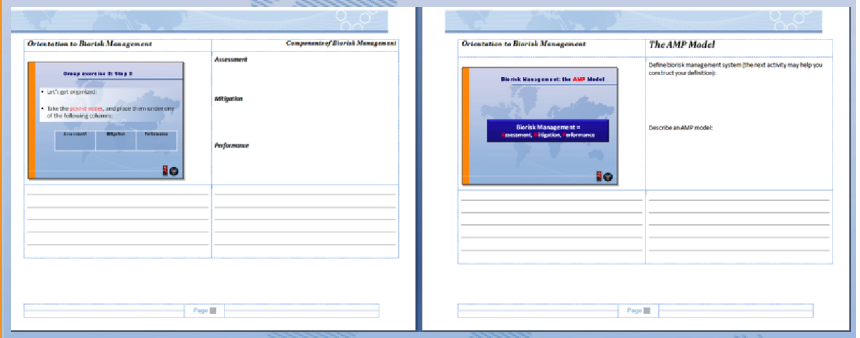
- Part I:
  - Lesson Overview
  - Student Description
  - Instructional Environment,
  - Resources
- Part II:
  - Course Outline

GBMRC Components: Slide Deck (SD)

GBRMC Components: Instructor Guide (IG)



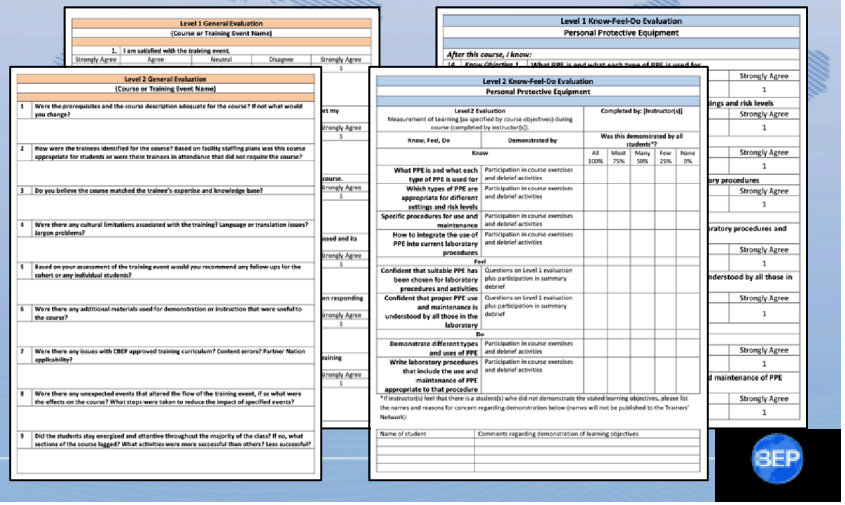
GBRMC Components: Student Guide (SG)



GBRMC Components: Evaluations (Level 1 – Level 2)

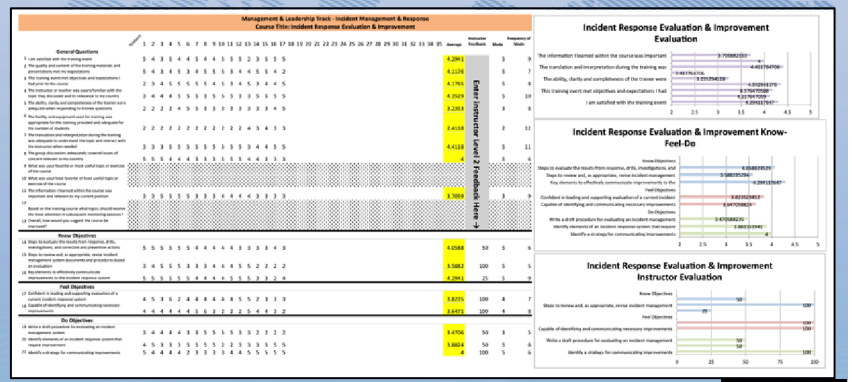
General

Course Specific
Know, Feel, Do



GBRMC Components: Evaluation Analysis Tools

Spreadsheet to Enter Evaluation Data
Pre-made Graphs



Public Access Site

- http://biosecurity.sandia.gov/gbrmc

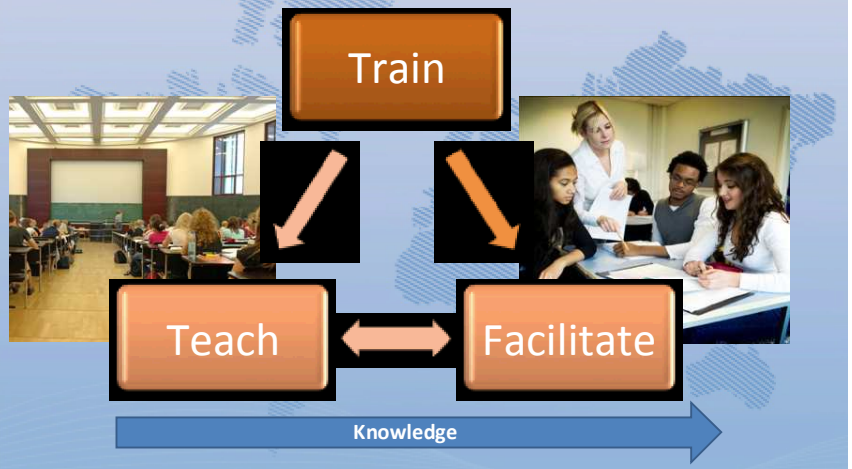
GBRMC Pillars – Training Techniques

- So what's different?
  - Experiential learning
    - Small group and plenary activities
    - Breaks
    - Movement & colors
    - Debriefs, recaps
  - Outcome based
    - What do you have?
    - Where do you want to go?

GBRMC Pillars – Training Techniques

- So what's different, continued?
  - Implementation "Blind"
    - No specific training scenarios anticipated
  - Comprehensive Toolkit
    - Detailed design document and instructor guide
    - Student guide and key references
    - Evaluations
  - Leave your fingerprints
    - Trainers' Network to capture feedback, solutions, configurations, customizations, revisions, translations, etc.

Facilitate versus Teach




Thank You!
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