



# Management Review

Ong Siew Kim  
MAACB, FAACB, MBA, PBT(ASCPI), EdD  
Project Coordinator

# Outline

- Describe the Management Review requirement in ISO 15189-2012
- Agenda of Management Review
- Quality Improvement activities

# Overview

- ✓ Day 1: Management Review lectures
- ✓ Day 2-3: Preparation of slides
- ✓ Day 4: Lab presentation to Hospital Dir
  - Each lab given only 30 mins
  - Timer for presentation

# Management Review

ISO – 15189 Clause 4.9; 4.14.6; 4.1.1.4; 5.2; 5.2.6

“Laboratory Management shall review the Quality Management System at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care”

# Management Review

ISO – 15189 Clause 4.9; 4.14.6; 4.1.1.4; 5.2; 5.2.6

“Laboratory Management shall review the Quality Management System at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care”

1. Regular management review of “Quality System” – [organizational structure, procedures and resources in place to ensure provision good quality service].
2. Audit of entire laboratory (12 sections)
3. At least one time in 1 year.

# Laboratory Role (QAO)

## Management Review

- ✓ Ensure that the meeting takes place
- ✓ Responsible for minutes of meeting
- ✓ Identify corrective action required
  1. Responsible person
  2. Timeline
  3. Ensure compliance & follow up
- ✓ Maintain all documentation.
- ✓ Discussions with Laboratory Management for next year plans.
- ✓ Same as overall objectives and strategies of the Hospital.

# Agenda for MR

1. Follow-up actions from previous management review (2019)
2. Organization chart (staff number, category, scope of work)
3. Year on year comparison of test volumes, types of test.
4. Continual improvement on identification and control of nonconformities (e.g. IQC, EQA).
5. Internal audits of all sections (e.g. Section 3 for this workshop).
6. Assessment of user feedback including of complaints.
7. Risk assessment of the whole lab process.
8. Reviews by external organizations - External Audits
9. Inter-laboratory comparison program (PT/EQA)

# Agenda for MR (continue)

10. Quality Indicators e.g. TAT (e.g. glu, CBC), critical results reporting (% within 1 hour), temp chart recording, blood culture contamination rate.
11. Review of requests, suitability of procedures and sample requirements (e.g. specimen rejection)
12. Health and Safety and environment.
13. Information Technology (e.g. CamLIS problems).
14. Equipment issues.
15. Performance of suppliers.
16. Recommendations for improvement, including technical requirements (e.g. improvement projects).
17. Staff suggestions.



# Quality Improvement Activities

1. Form a team. Must have outcome and completion time.
  2. Design a study e.g. use of statistic, PDSA, Ishikawa diagram, FMEA.
  3. Report progress to management and laboratory
- Examples QI projects: correct actions, preventive actions, customer's suggestions or complaints, errors or opportunities for learning from occurrence management program, internal audits deficiencies, non-conformity.

# Management Review Output

A record that documents any decisions made and actions taken during management review on:

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A record that documents any decisions made and actions taken during management review on:

- a) improvement of the effectiveness of the quality management system (QMS);
- b) improvement of processes;
- c) improvement of services to users;
- d) resource needs.

# Management Review Presentation

## Outline

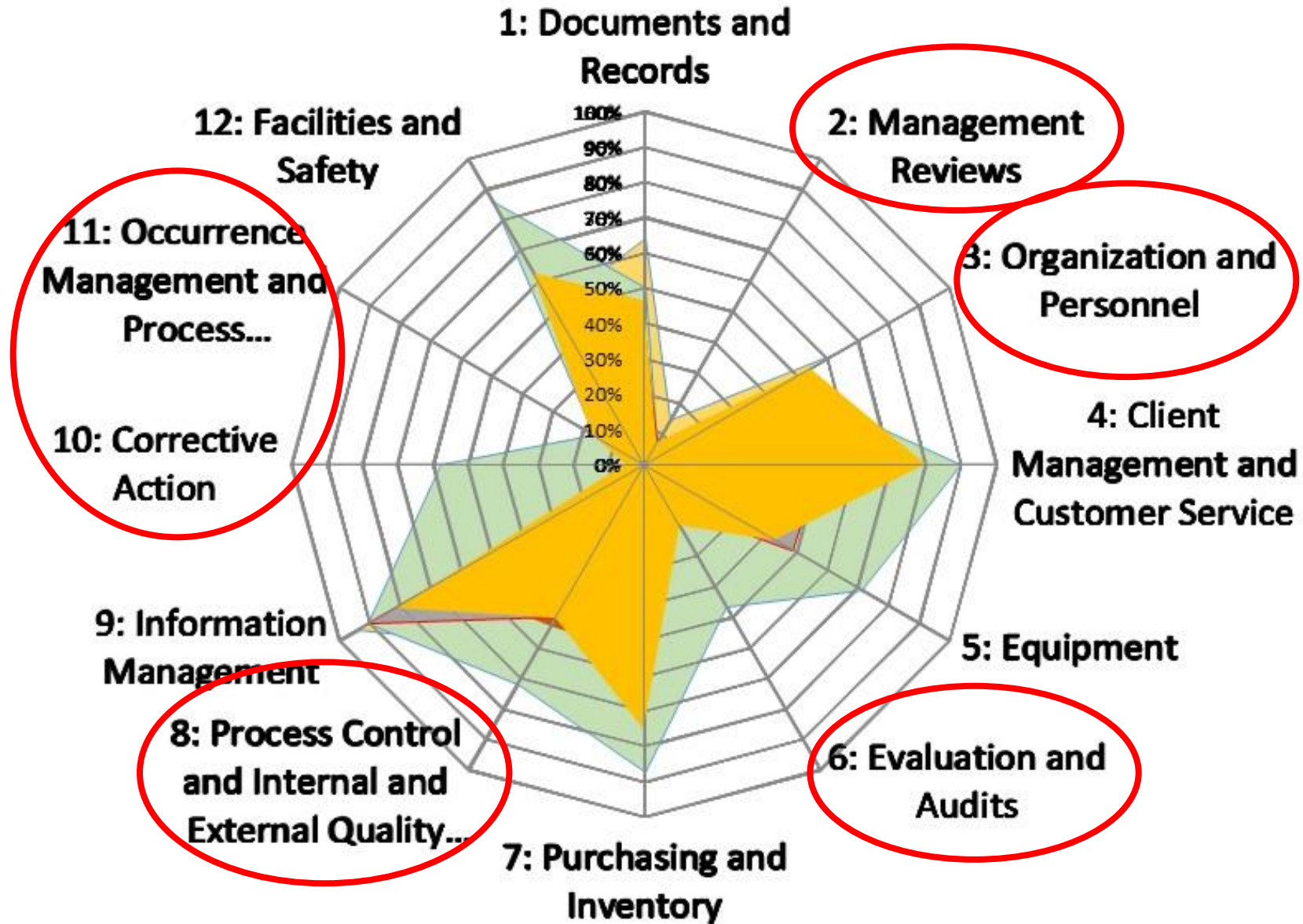
- Summary of 2018 activities
- Some power point presentation tips
- Show charts and graphs construction

# Strategy 2018

Baseline  
Audit



Feb



# Strategy 2018: On-site training

Baseline  
Audit



Kg Cham



CamLQMS

IQC, EQA



Lab Statistics

Equipment & evaluation

Stock

Feb

Mar

# Strategy 2018: On-site training

Baseline  
Audit



KCM, PKH, Takeo

Kg Cham

Feb

Mar

April



# Example: Lab Walk-through on IQC out-of-range explanation



# Pipette calibration check training



Correct pipetting technique



# Distiller and clinical lab reagent water



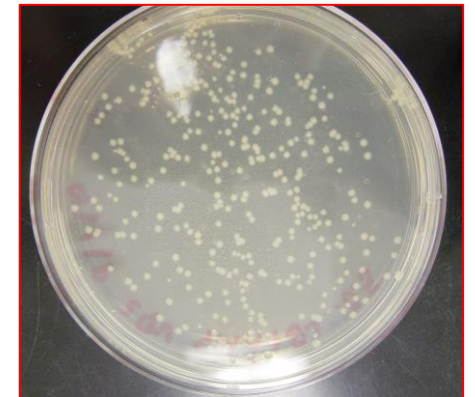
Distiller



Opaque container



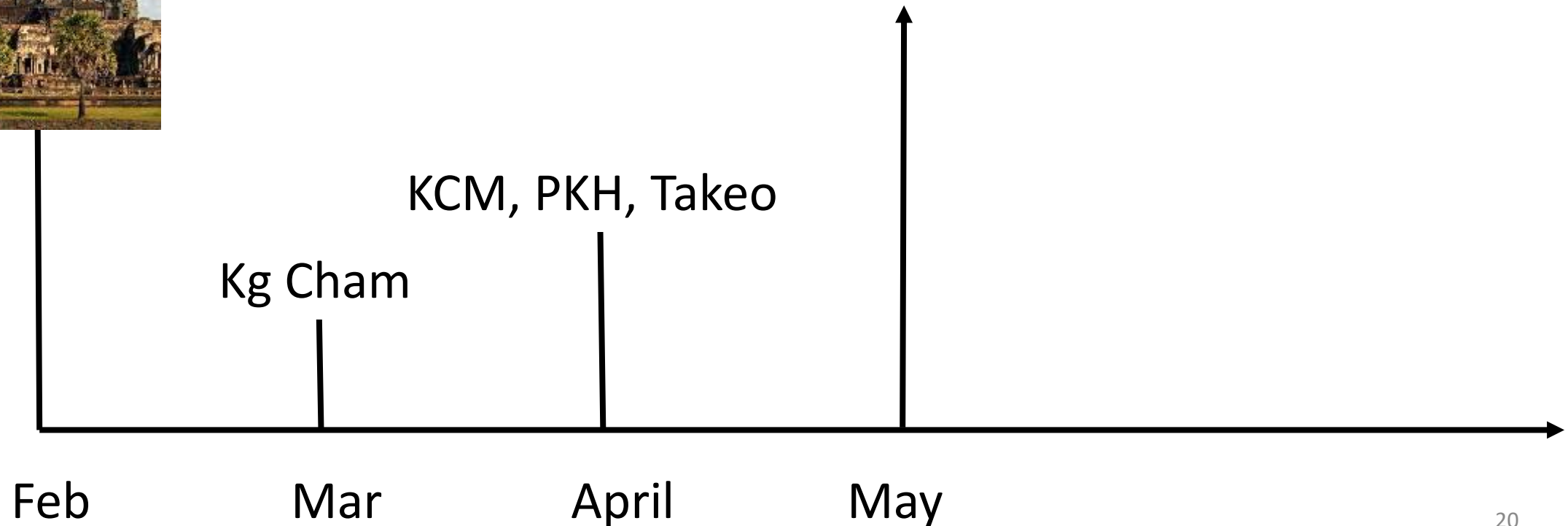
Filtration  
<math><0.22\mu\text{M}</math>



Colony counts

# Strategy 2018: On-site training

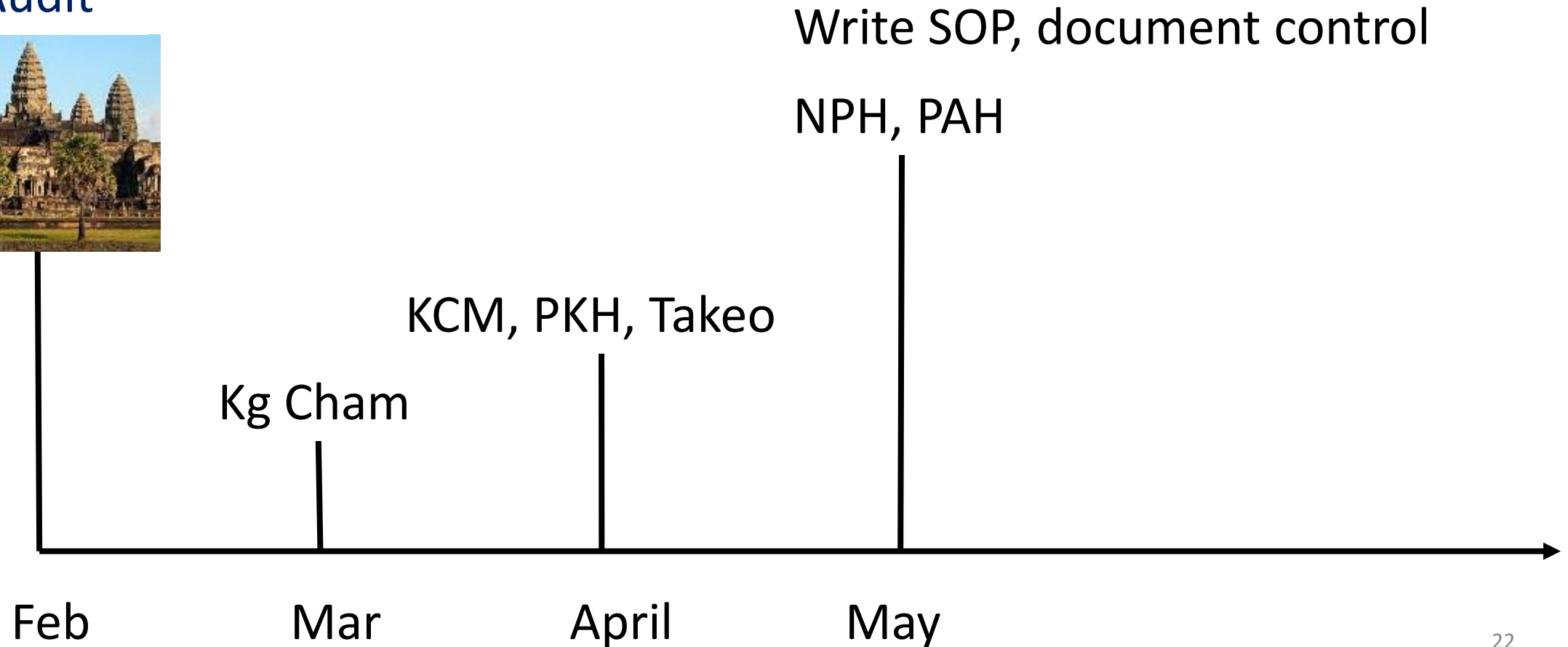
Baseline  
Audit





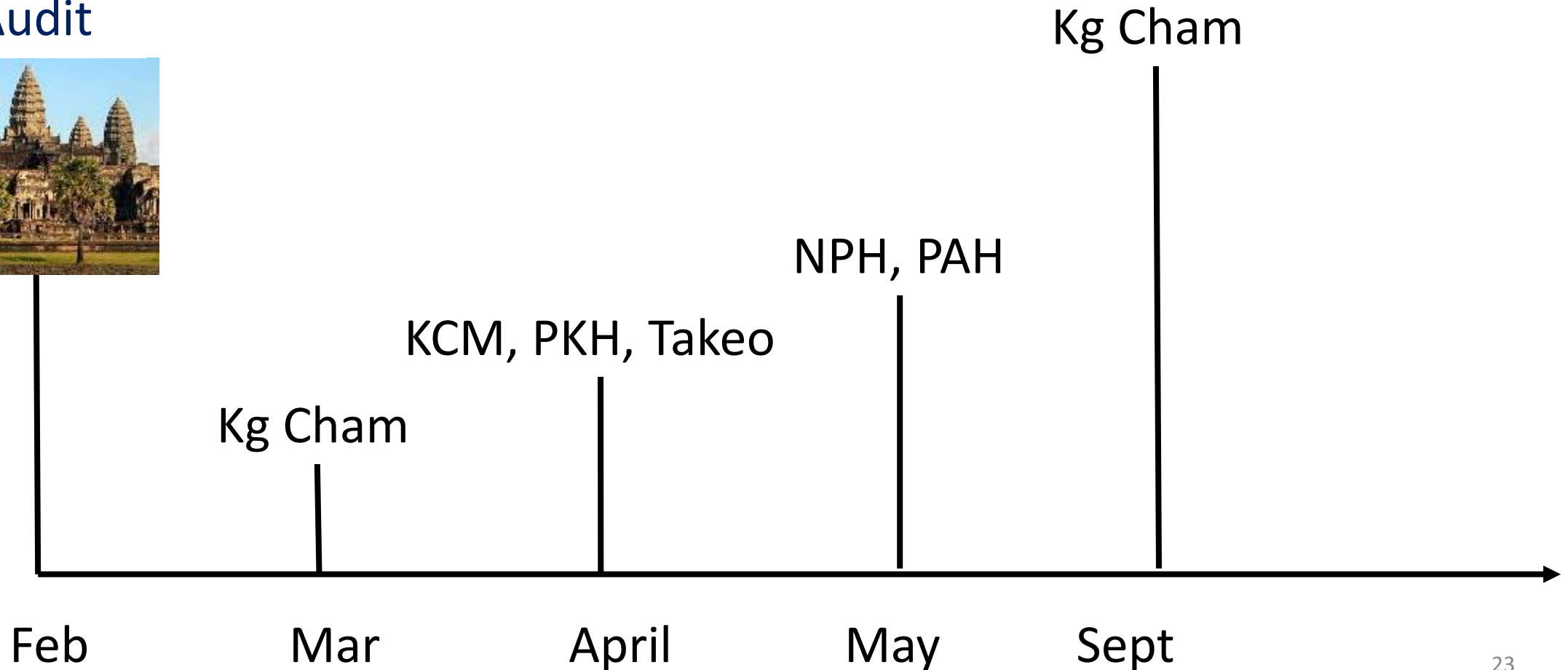
# Strategy 2018: On-site training

Baseline  
Audit



# Strategy 2018: On-site training

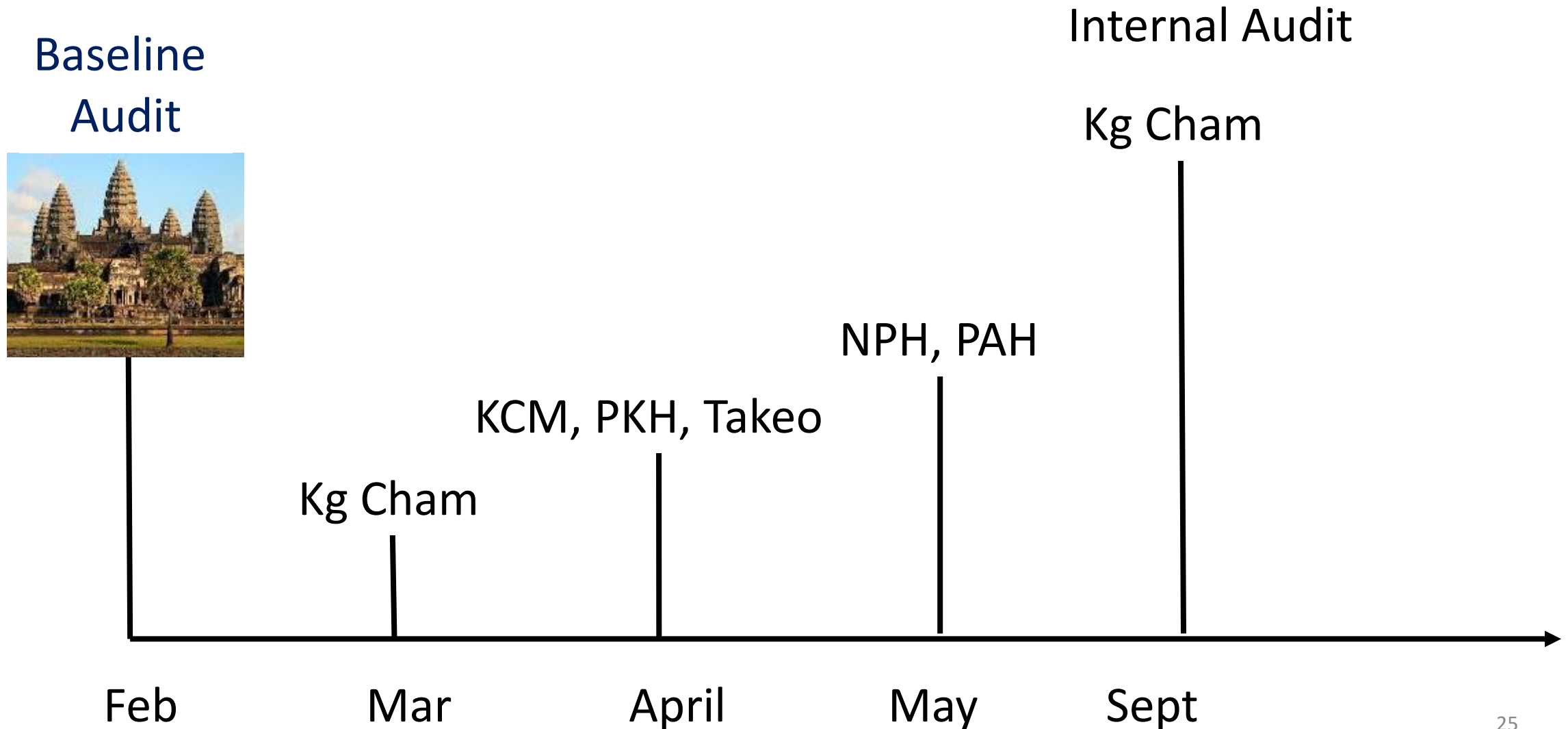
Baseline  
Audit





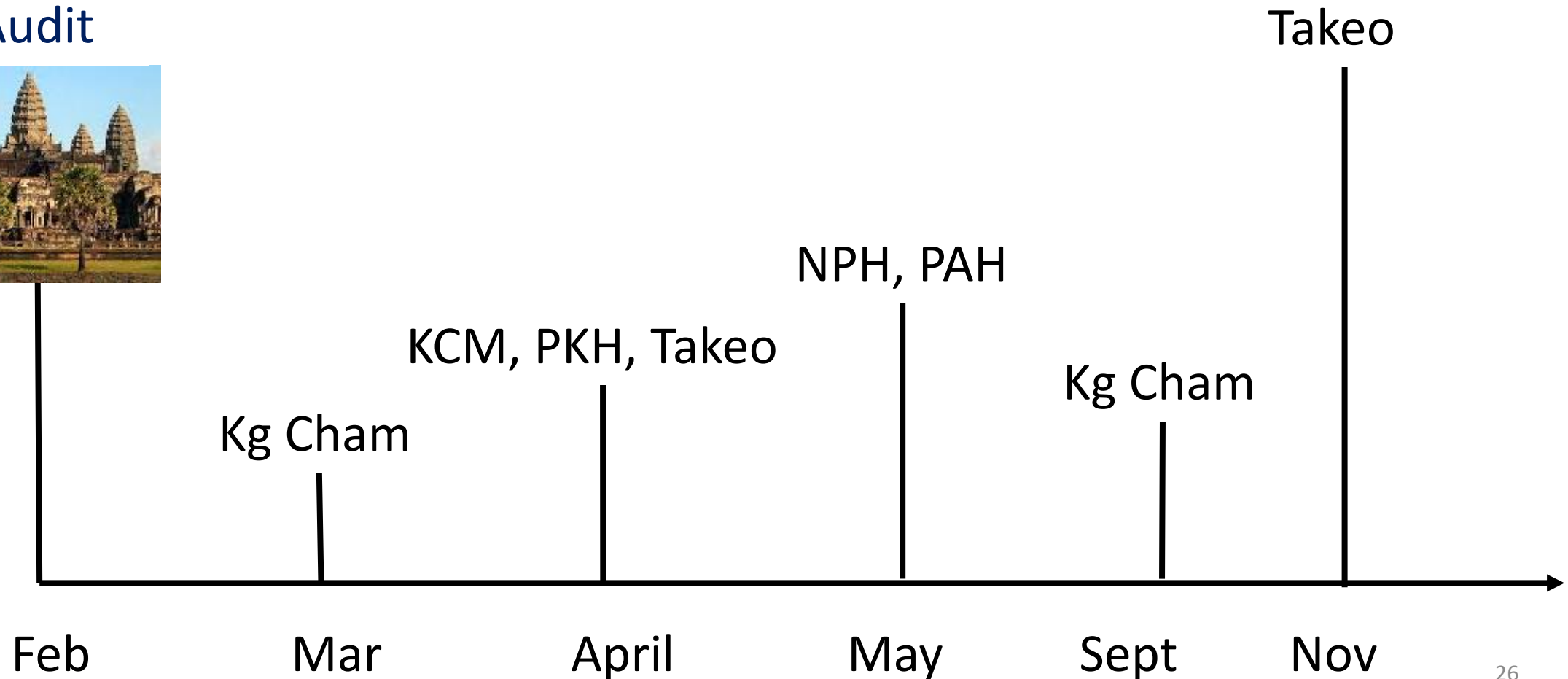


# Strategy 2018: On-site training



# Strategy 2018: On-site training

Baseline  
Audit



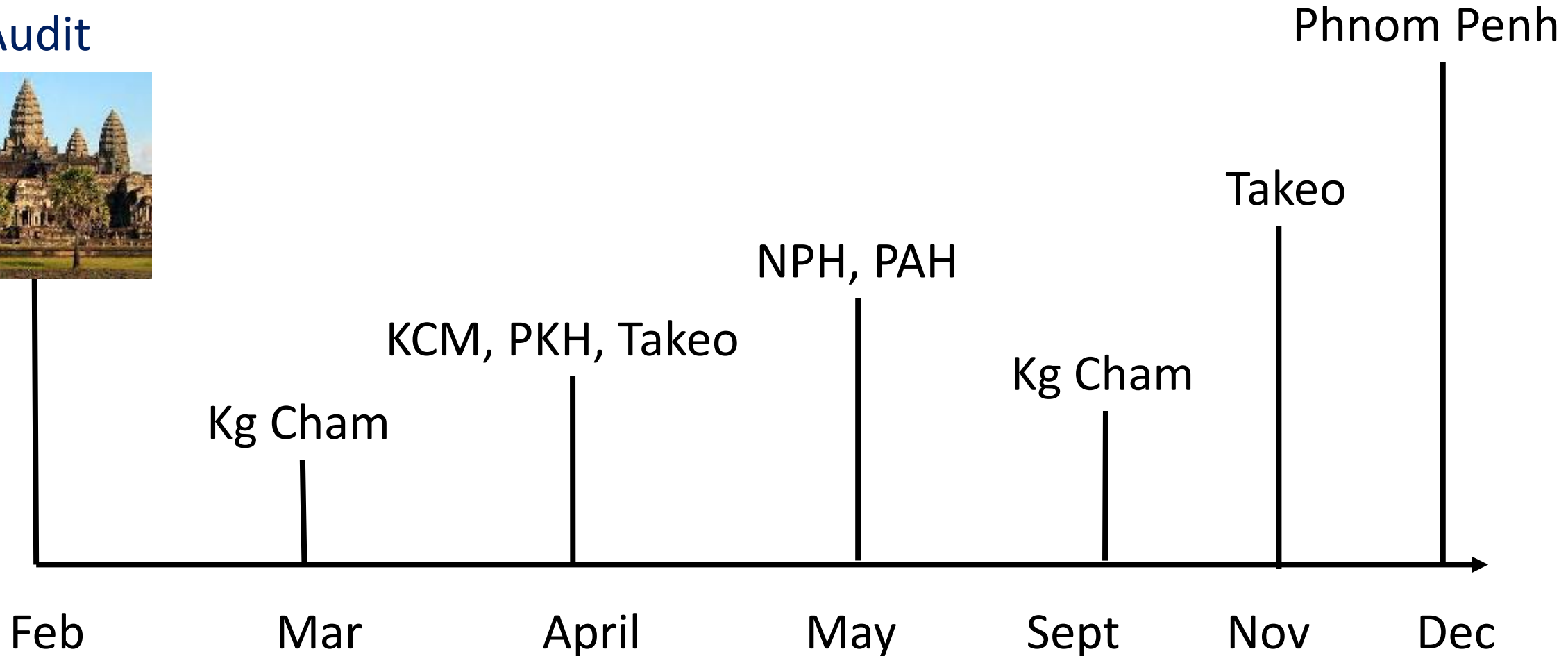
# Method verification

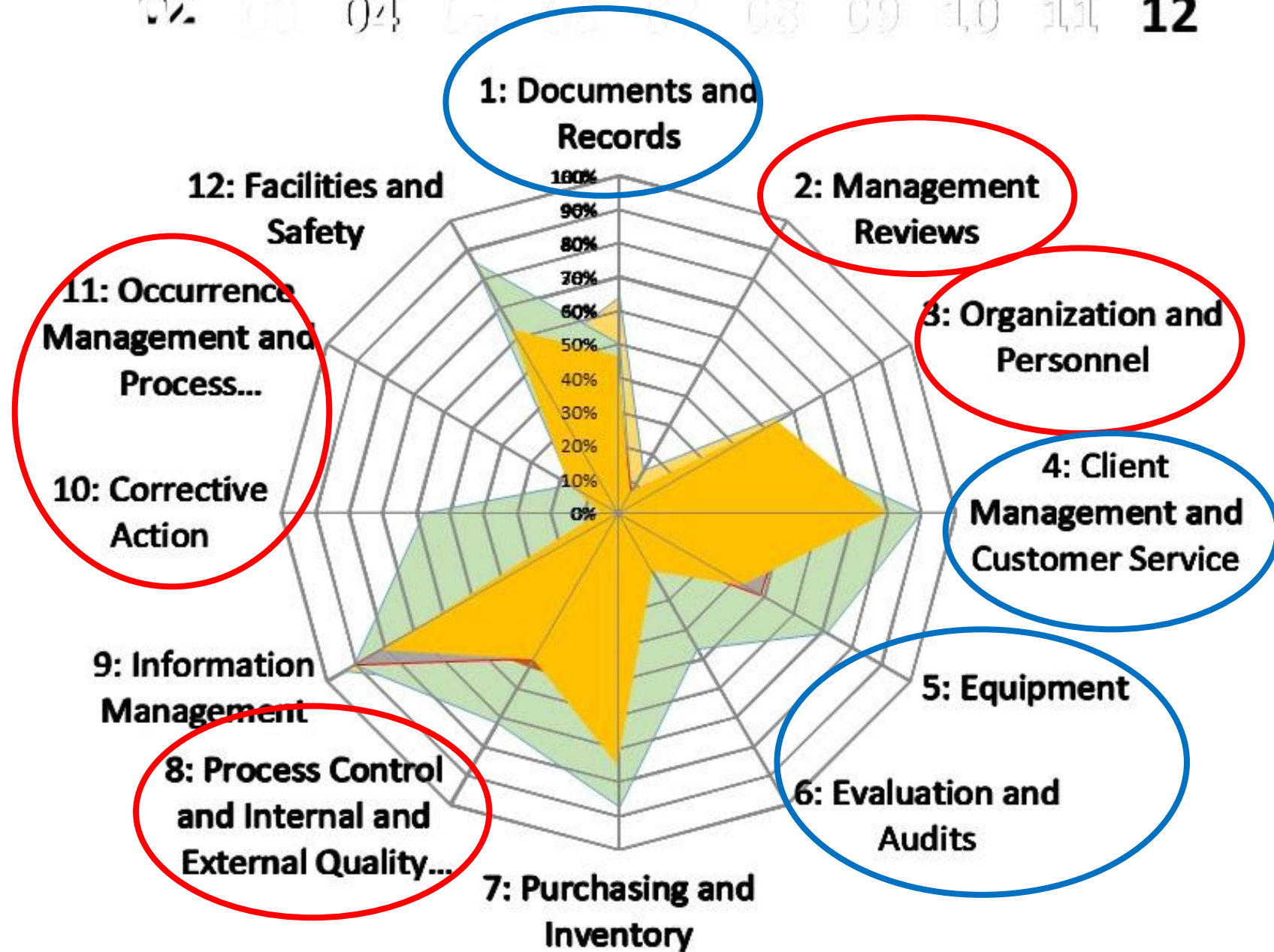


# Strategy 2018: On-site training

## 6 on-site workshops

Baseline  
Audit





# CamLQMS Scores

- ✓ Complete all the 6 on-site training practices (2018)

- ✓ Remote mentoring:

Dec 31, 2018 - March 1, 2019

# Tentative Final CamLQMS Audit Schedule 2019

Date	Lab	Audit Team		
		I-TECH Team	Auditor Trainee	BMLS
Mar 3 – 7, 2019	Kratie	Siew Kim		
	PAH			
Mar 10 -15, 2019	Prey Veng			
	Svay Rieng			
Mar 18 -22, 2019	Kg Cham	Audit Consultant		
	Kossamak			
	Sihanoukville	Nayah		
	Kampot			
Mar 25 – 28, 2019	Takeo	Audit Consultant		
	NPH			
	KSFH	Nayah		
	Kandal			

# Some power point presentation tips

1. Keep it simple

2. Choose your fonts

3. Use appropriate charts/graphs/tables

4. Use color



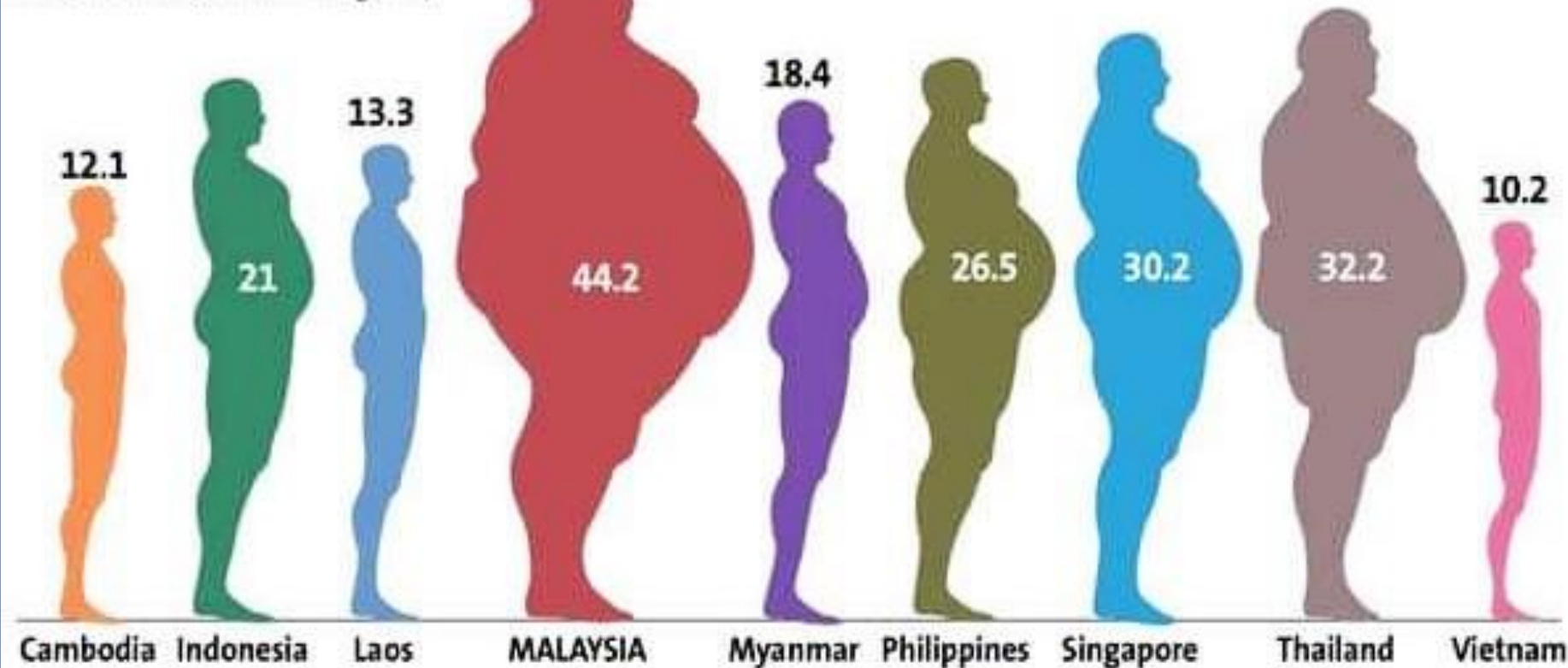
# 1. Keep it simple

✓ Use pictures

✓ Less words

## Overweight populations in southeast Asia

Overweight prevalence (%) for adults of both sexes (BMI of > 27kg/m<sup>2</sup>)



Source: WHO Non-Communicable Diseases Country Profiles, 2011

## 2. Choose your fonts

- ✓ Use 1 or 2 types of font
- ✓ Font size: can be seen at the back of the room

Example: size 24 or bigger

Calibri 28

Font size

Fonts

Theme Fonts

- Calibri Light (Headings)
- Calibri (Body)

Recently Used Fonts

- Century Gothic
- Times New Roman

All Fonts

- Agency FB
- ALGERIAN
- Arial
- Arial Black**
- Arial Narrow
- Arial Rounded MT Bold**
- Bahnschrift
- Bahnschrift Condensed**
- Bahnschrift Light
- Bahnschrift Light Condensed
- Bahnschrift Light SemiCondensed
- Bahnschrift SemiBold**
- Bahnschrift SemiBold Condensed**

Century Gothic Font 18

I can read

Font size

Century Gothic Font 24, 28, 32, 36

I can read

I can read

Times New Roman Font 18

I can read

I can read

Font 24

I can read

I can read

Font 28

I can read

Font 32

I can read

Font 36

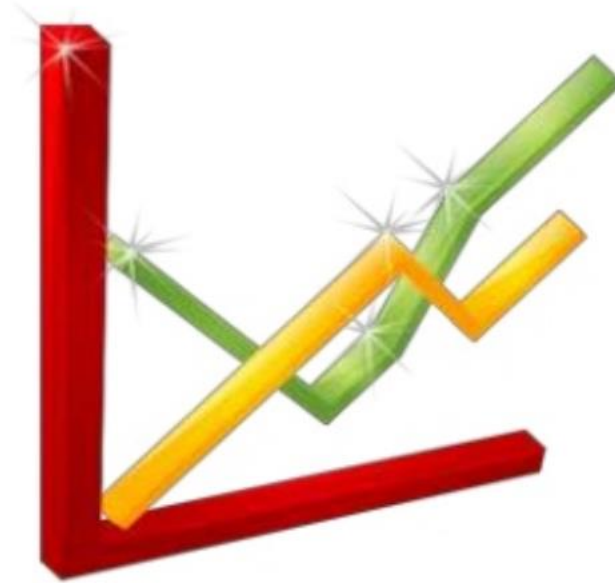
I can read

# 3. Use appropriate charts/graphs

Bar chart



Line chart



Pie chart



File Home **Insert** Design Transitions Animations Slide Show

New Slide Slides Table Tables Pictures Online Pictures Screenshot Photo Album Shapes Icons 3D Models SmartArt Chart

AutoSave Off Save Undo Redo

### Insert Chart

All Charts

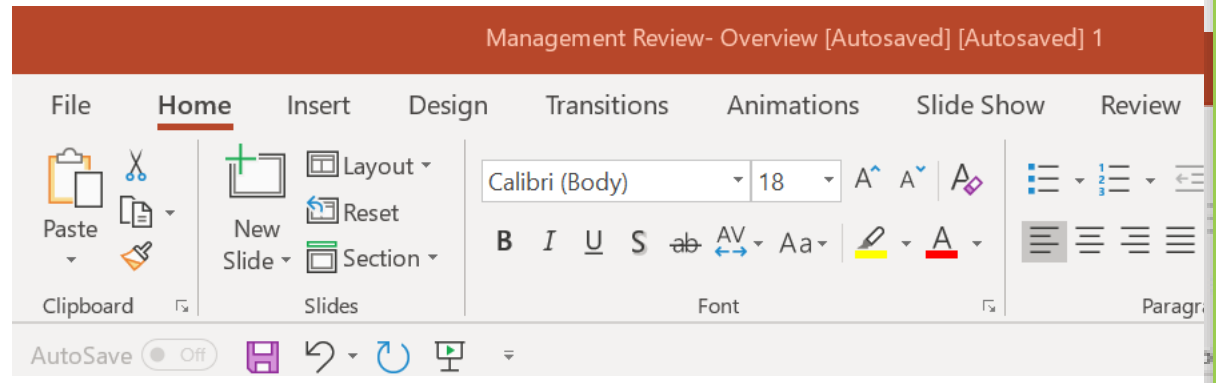
- Recent
- Templates
- Column
- Line
- Pie
- Bar
- Area
- X Y (Scatter)**
- Map
- Stock
- Surface
- Radar
- Treemap
- Sunburst
- Histogram
- Box & Whisker
- Waterfall
- Funnel
- Combo

#### Scatter

X	Series 1 (Y)	Series 2 (Y)
1	0.5	2.7
2	1.8	3.2
3	2.6	0.8

OK Cancel

# 4. Use color



### Colors

Standard Custom

OK Cancel

Colors:

New

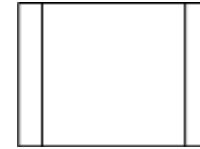
Current

The 'Colors' task pane is open, showing the 'Standard' tab. It features a large hexagonal color palette with a yellow hexagon selected. Below the main palette is a horizontal color bar with various shades of gray and black. On the right side, there are 'OK' and 'Cancel' buttons. At the bottom, there are 'New' and 'Current' labels with corresponding color swatches (yellow and purple).

# Work Process



Start/End



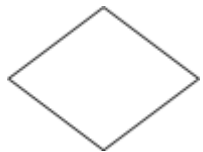
Sub-Process



Process



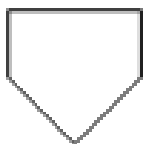
Document



Decision (question)



Data



Off-page reference

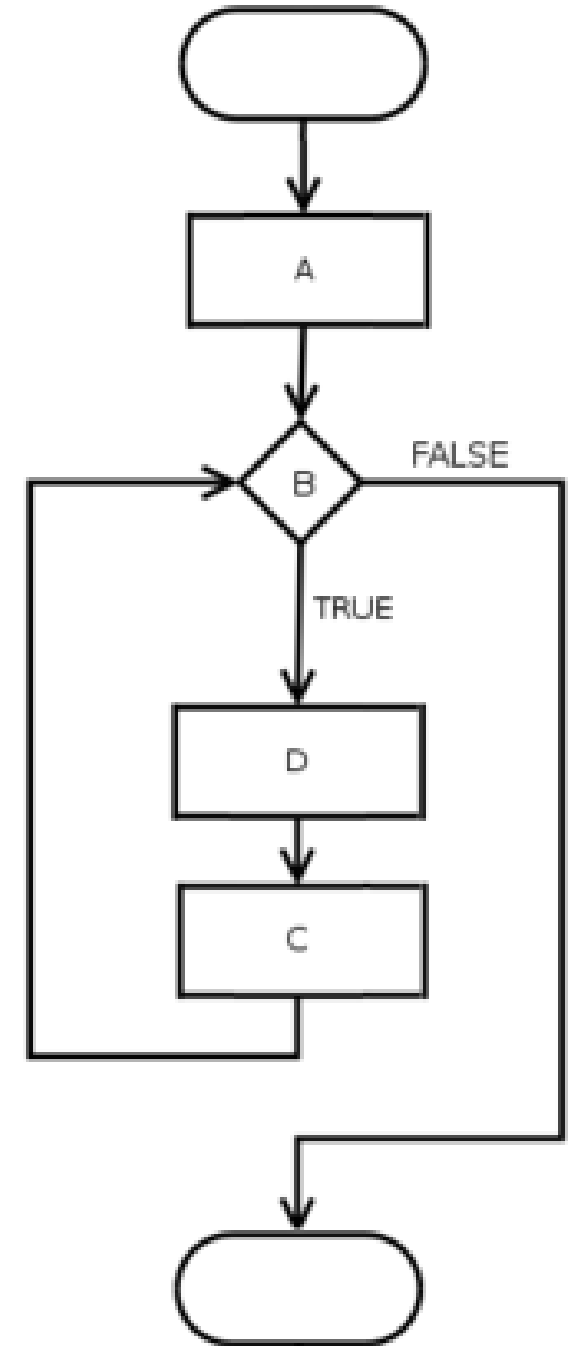
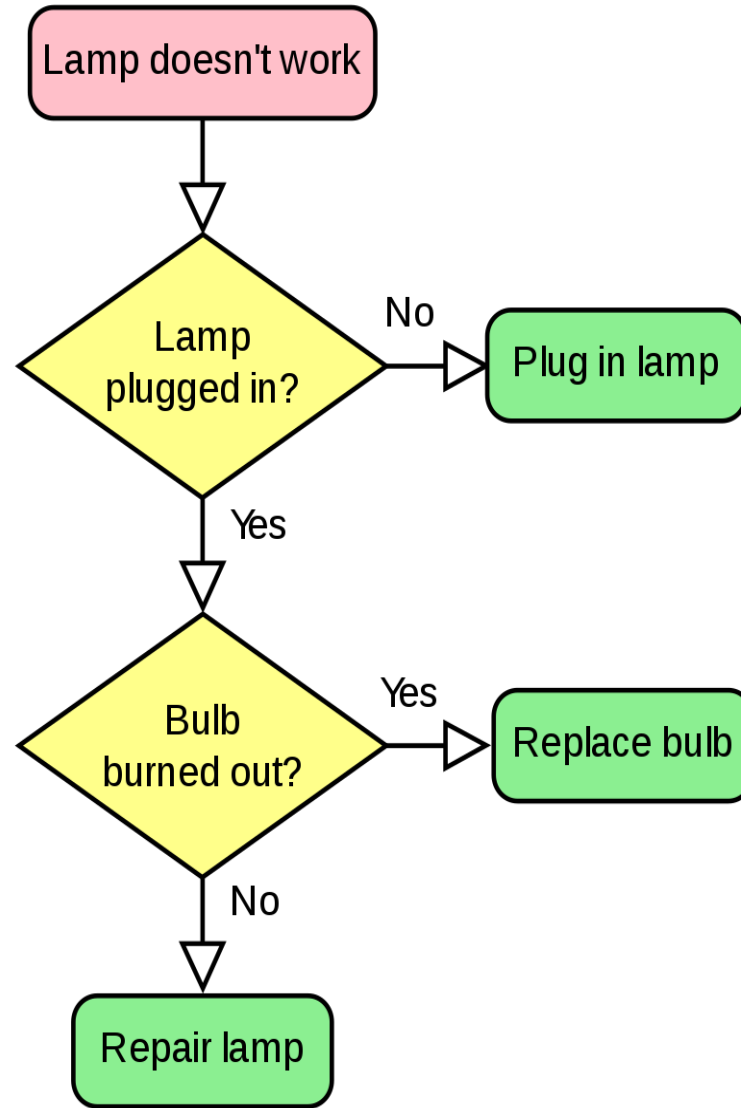
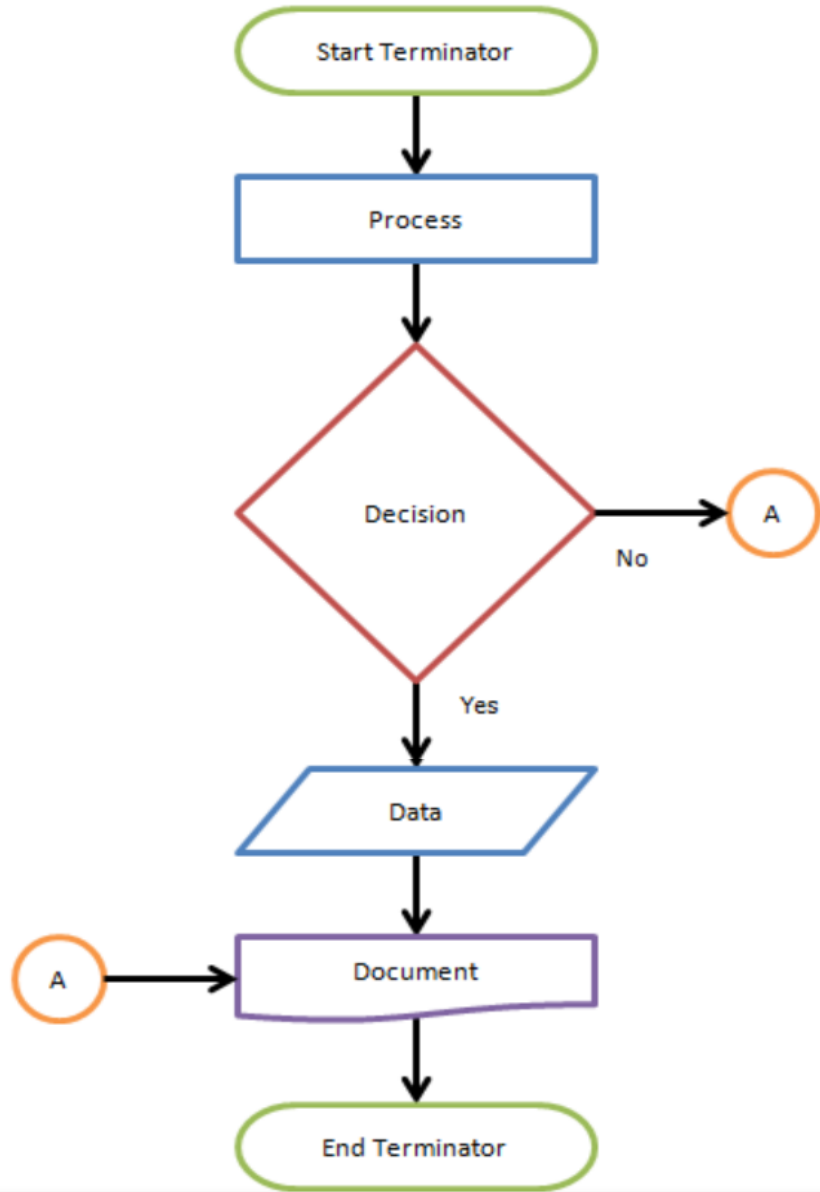


On-page reference

[Click](#)



# Examples: Work flow charts



# Effective implementation/operation according to ISO 15189

Examples of assessment: 1. Internal audits

2. Occurrence management

3. Document control

4. Risk management

# Effective implementation/operation according to ISO 15189

## 1. Internal audits

- Assessing implementation and effectiveness of process.
- All 12 sections in 1 yr.
- Results are based on facts and data.
- Continual improvement to perform better.

# Effective implementation/operation according to ISO 15189 - *continued*

## 2. Occurrence management

- Resolution of nonconformities.
- Root cause analysis (RCA).
- Process of quality improvement.
- Corrective action and preventive action.

# Effective implementation/operation according to ISO 15189 - *continued*

## 3. Document control

- Procedures signed on time,
- Eliminate outdated information.
- Finding a document during an accreditation visit.
- Staff can find the document in the shortest time.

# Effective implementation/operation according to ISO 15189 - *continued*

## 4. Risk management

- There is process owner, process map, and identify its risk points.
- Identified during internal or external audits (e.g. EQA)
- Identify future risks based on past errors.
- All staff to support identifying risks

Name what are the good  
quality activities

How does the lab achieve  
these?

- What?

- Things to do

# Summary

- Why do Management Review?
- What are the components in Management Review?
- Do a presentation on Management Review



# Friday Dec 21, 2018 zoom calls

Zoom

11. PAH\_QI monitoring and data collection - Excel

Sophanna Song

File Home Insert Page Layout Formulas Data Review View Help Power Pivot Tell me what you want to do Share

Clipboard Font Alignment Number Styles Cells Editing

E5

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z AA AB AC AD AE AF AG

**Preah Angduong Hospital Laboratory** **Daily Critical Result Monitoring Table** Month:.....

Test\Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1 White Blood Cells (WBC)																															
2 Hematocrit (Ht)																															
3 Hemoglobin (Hb)																															
4 Platelet																															
5 Prothrombin Time (PT)																															
6 Glucose (fasting)																															
7 Calcium																															
8 Glycosylated Hb (HbA1C)																															
9 Urea/BUN																															
10 Creatinine																															
11 AST/SGOT																															
12 ALT/SGPT																															
13 Amylase																															
14 Cholesterol, total																															
15 Triglycerides																															
16 Sodium (Na)																															

PAH\_QI | Data collection | M. Temp. | D. Temp. | M. Equip. | D. Equip. | M. SRej. | D. SRej. | M. IQC | D. IQC | M. Cri. Result | D. Cri. Result | D. NCs | D. TAT ...

Page: 1 of 1

11:36 AM 21-Dec-18

Participants (7)

- Kim Ong (Me)
- Song Sophanna (Host)
- hay lor
- savuth kampot
- Khum Ravy PKH
- Malin Chao
- Malin Chao

Raise Hand yes no go slower go faster more

**Song Sophanna**

**Kim Ong**



Hay Lor

**Malin Chao**

**Samrach ( Lab S...**

**IN Thida PAH**



**sam rach SVR lab**

**Malin Chao**



Messenger x Launch Meeting - Zoom x +

https://www.facebook.com/messages/t/theara.oudom

Apps Zoho Google Facebook English-Khmer Dictio Google Translate SPN Yahoo Mail Labtest online Mail - sophonassong Other bookmarks

Download Forward

Info

Accuracy/Correlation Study

Background: Preah Kosamak Hospital current method is HIS200. Verification study with new analyzer Dimension.

Study	Criteria	Pass/Fail
Slope: 0.999	1.50	Pass
Intercept: 2.393	< 10%	Pass
Correlation: $R^2 = 0.999$	> 0.95	Pass

Conclusion: The new Dimension Verification is acceptable.

Prepared: \_\_\_\_\_ Date: \_\_\_\_\_

*Plan* *Reference Paper*

- Participants (5)
- Kim Ong (Host, me)
  - Oudom (Kandal)
  - Song Sophanna
  - Vanna's iPhone
  - Angduong IN Thida

yes no go slower go faster more clear all

Mute All Unmute All More

Windows taskbar icons: File Explorer, Edge, Chrome, Firefox, Word, PowerPoint, Zoom, etc. 2:01 PM 21-Dec-18

Windows taskbar icons: File Explorer, WhatsApp, Skype, Edge, Chrome, Outlook, Word, Zoom. 2:01 PM 12/21/2018

Windows taskbar icons: Help, Network, Bluetooth, Wi-Fi, Cloud, Battery, 2:01 PM 12/21/2018

# Friday Dec 21, 2018 zoom calls

Zoom

11. PAH\_QI monitoring and data collection - Excel

File Home Insert Page Layout Formulas Data Review View Help Power Pivot Tell me what you want to do

Calibri 11 A<sup>+</sup> A<sup>-</sup> Wrap Text Merge & Center

General \$ % .00 →0

Clipboard Font Alignment Number Styles Cells Editing

C31 < 40 mg/dL, > 400 mg/dL

Critical Test and Critical Result	
1 White Blood Cells (WBC)	> 30.0 x10 <sup>9</sup> /L
2 Hematocrit (Ht)	< 20% , > 60%
3 Hemoglobin (Hb)	< 5.0 g/dL , > 20.0 g/dL
4 Platelet	< 20 x10 <sup>9</sup> /L , > 1000 x10 <sup>9</sup> /L
5 Prothrombin Time (PT)	> 30 seconds or >2.5 INR
6 Glucose (fasting)	< 40 mg/dL, > 400 mg/dL
7 Calcium	< 4.4 mg/dL, > 13.0 mg/dL
8 Glycosylated Hb (HbA1C)	> 8.1%
9 Urea/BUN	> 100 mg/dL
10 Creatinine	> 10 mg/dL
11 AST/SGOT	> 20,000 U/L
12 ALT/SGPT	> 9000 U/L
13 Amylase	> 1000 U/L
14 Cholesterol, total	> 300 mg/dL
15 Triglycerides	> 500 mg/dL
16 Sodium (Na)	< 125 mmol/L, > 160 mmol/L
17 Potassium (K)	< 2.5 mmol/L, > 8.0 mmol/L
18 Chloride (Cl-)	< 70 mmol/L, > 120 mmol/L
19 T3	< 50 ng/dL, > 300 ng/dL
20 T4	< 2.0 µg/dL, > 20 µg/dL
21 TSH	<0.1 mIU/L

Close

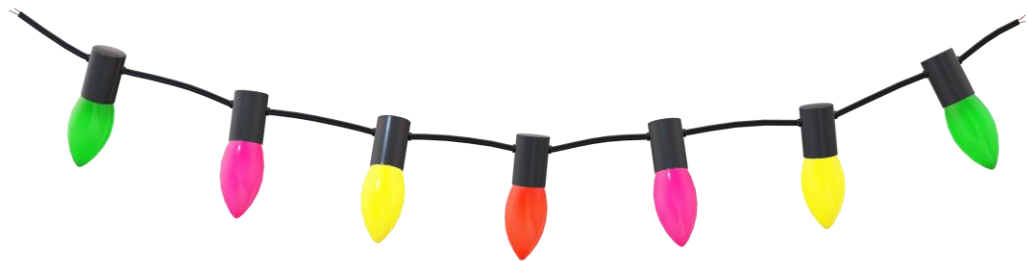
## Participants (7)

- Kim Ong (Me)
- Song Sophanna (Host)
- hay lor
- Khum Ravy PKH
- savuth kampot
- Malin Chao
- Malin Chao



Unmute Me

Reclaim Host



Merry Christmas!

