Audit Planning and Preparation

Audit Process

...The PDCA cycle also applies to the Audit Process...

Report to Management Review

Planning

Performing

Reporting

Follow - up
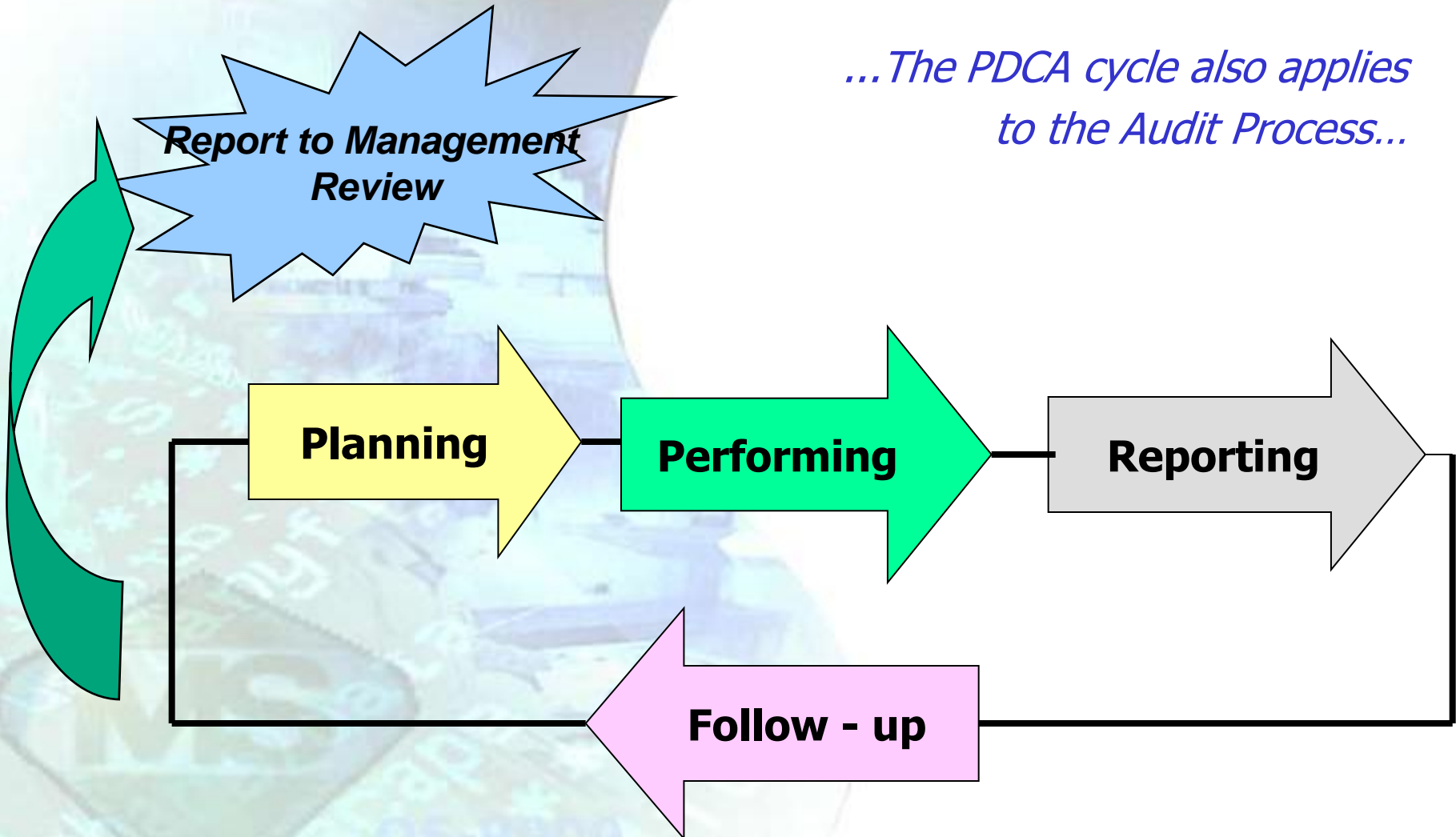
Audit Process

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                    ┌─────────────────────┐
                    │   Internal Audit    │
                    └─────────────────────┘
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Planning	Execution	Reporting	Follow-up
- Auditor Selection	- Opening Meeting	- Finding Classification	- Identify Root Cause
- Audit Schedule	- Collect Information	- Report Writing	- Corrective Action
- Audit Plan	- Verify Information	- Report Distribution	- Verification
- Notify the Auditee	- Closing Meeting		
- Prepare Audit Checklist			

Audit Program

- An audit program will be influenced by the following criteria:
    - The scope, objective and duration of each audit to be conducted.
    - The number, importance, complexity, similarity and locations of the activities to be audited.
    - Standards, statutory, regulatory and contractual requirements and other audit criteria.
    - Result of previous audit.
    - Significant changes to an organization or its operations.
- Output of audit program - Auditor selection, audit schedule and audit plan.

Internal Audit Programme for YEAR 2008
(Example)

Laboratory:_____

No.	Process	Jan	Feb	Mac	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Management processess		🟨										
2	Equipment maintenance		🟨										
3	Purchasing		🟨										
4	Test reports		🟨										
5	Test methods		🟨							🟨			
6	Customer Satisfaction		🟨										
7	Training		🟨										
8	Sample reception, storage		🟨										

Prepared by:
Date:

Approved by:
Date:

Audit Timetable

An audit plan identifies the following items:

• The tentative date and place of the audit
• The auditee and organizational units to be audited
• The audit team members
• The scope and purpose of the audit
• The standard being audited against
• The expected duration of the audit
• The time for the start opening meeting and end of closing meeting

Sample of Audit Timetable

#	Date: Wed 8/11 Time:	Activities	Auditor
1	0900-0915	Opening meeting	All
2	0915-1230	• Organisation, purchasing, management review, test reports, record control	Mustafaa
3	0915-1230	• Water Lab – sample management, staff competency, equipment management, accommodation and environment	Farah
4	0915-1230	• Pesticide Lab – sample management, staff competency, equipment management, accommodation and environment	Nurul
5	0915-1230	• Food Lab – sample management, staff competency, equipment management, accommodation and environment	Ili

Audit Team

Once the objectives, scope of the audit have been decided, the auditor(s) can be selected.

The basis of selection shall be based on:
• the independence of the area audited,
• audit training and
• knowledgeable on the area/activity audited.

Although knowledge is not mandatory but it is an essential qualification in ensuring a more significant to audit effectiveness

Notify The Auditee: Purposes

(1) Confirm the authority to conduct the audit

(2) Provide information on proposed audit timing and audit team composition

(3) Request access to relevant information , including records

(4) Determine applicable site safety rules

(5) Make arrangements for the audits

EVALUATE MANAGEMENT SYSTEM

Study of the system documentation.

Documentation may include:
- Quality Manual
- Specifications
- Standards
- Procedures
- Work Instructions
- Customer complaint file
- etc.

PREPARATION   OF CHECKLISTS

List the items to be taken into the audit as a reminder e.g.

- Audit plan and checklist
- Copies of QA manual, departmental procedures, work instructions, etc.
- Copy of the Standards (e.g. ISO 17025)
- Note book
- Nonconformance reports/Corrective Action Request forms.
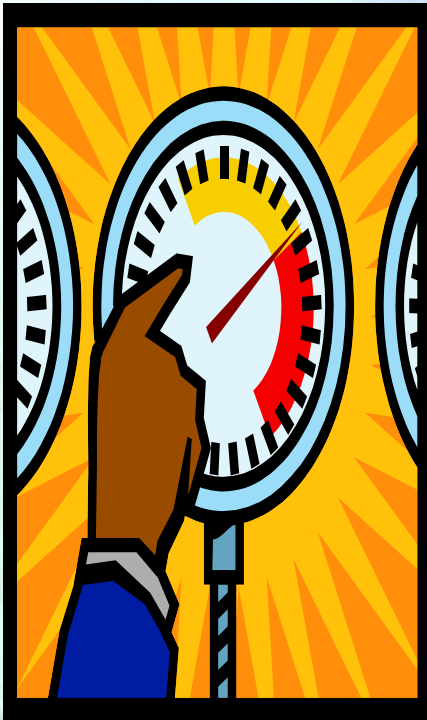
AUDIT CHECK LIST

- Assists in conducting Audit
- Assures thoroughness and consistency
- Identifies essential points to be examine
- Identifies necessary evidence/samples
- Cross reference to standards identified
- Maintains audit direction

Preparation of audit checklists

Types of Checklist

Questionaire checklist

- This can be done by comparing the statement of the Standard and then turning the statement into a question

  e.g.: 4.3 - Control of Documents

Requirement	Checklist Question
A documented procedure shall be established to define the controls needed to…	Does the org establish…? / Is there evidence that the org…?/ What proc available to ensure that doc are controlled?

Preparation   of checklists

Types of Audit Checklist

Word prompt checklist

• In the form of word prompt listed to remind the auditor on what to investigate

Eg 4.3 Control of Documents

Requirements	Observations	
	NOTES	**N/C**
4.2.3 Documented Procedure **4.2.3(a) Approval of documents** **4.2.3(b) Review & update** **4.2.3(c) Changes…**		

Typical checklist questions

- **What are the equipment used in the laboratory?**

- **Are the equipment calibrated and traceable to international standards ?**

- **How do you evaluate the supplier ?**

- **What are the reagents used in the test?**

- **How do you handle complaints?**

- **What is the quality control method used to ensure quality of tests ?**

Typical questions about test methods

- What is the test method used to analyse the sample?

- How is the method documented ?

- Is the actual practice conform to actual documentation?

- How do you ensure the test procedure is valid?

- Who controls the test procedure ?

- Who approves the test procedure?

Typical questions about equipment

- What are the testing equipment used ?

- How are the equipment maintained?

- Are the equipment used according to proper methods?

- What are the calibration program provided ?

- Who are authorised to operate the equipment ?
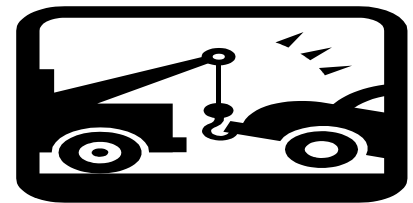
Typical questions about training and competency

- **Who is responsible for this test?**

- **Who trains the tester ?**

- **What is the competency required to perform the test?**

- **What is the competency level of the personnel operating the equipment?**

- **What are the training plans ?**

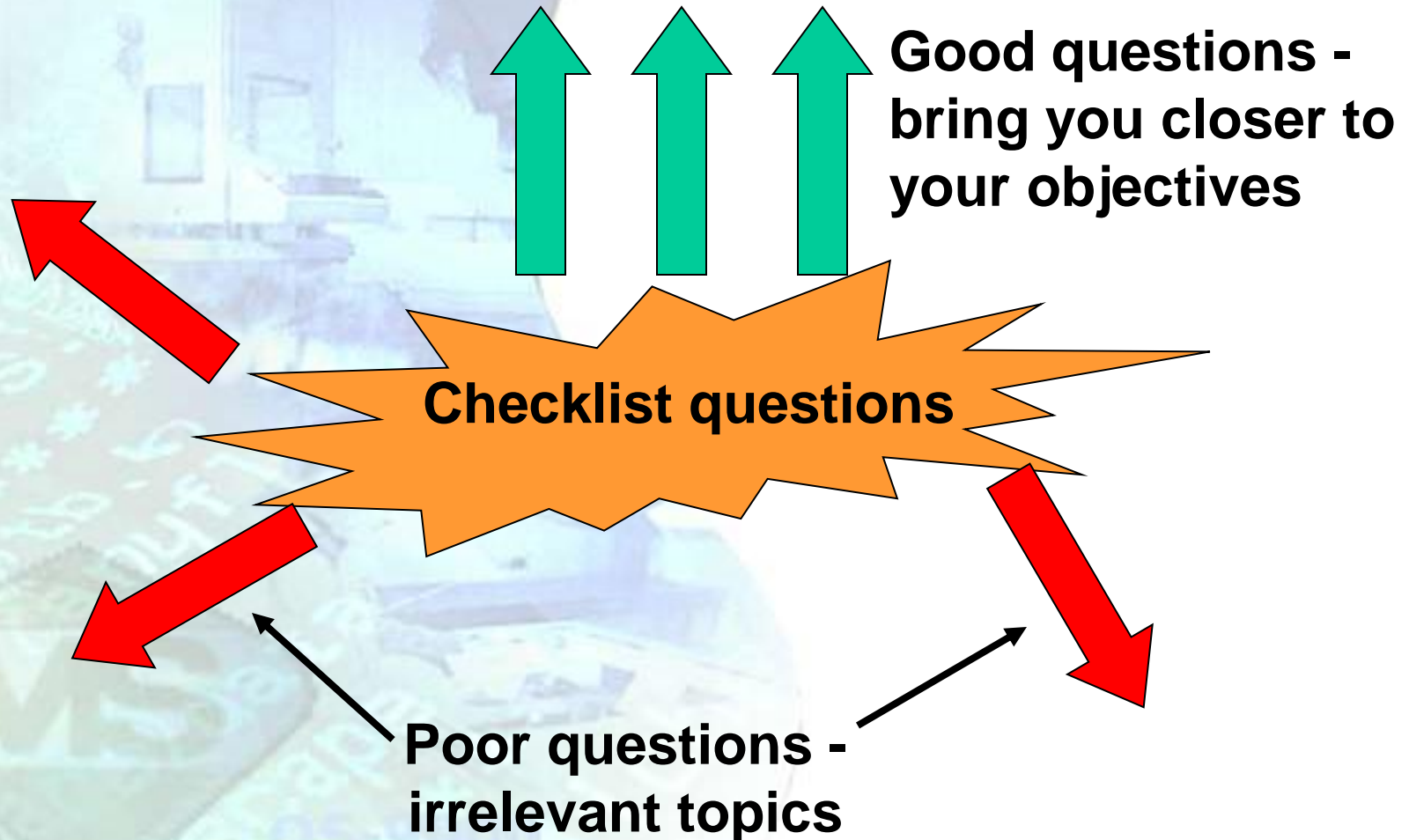- **How do you evaluate the effectiveness of the training?**

Dangers With Checklists

- Relying too much on checklist and ignoring what is going around

- As checklists are prepared in advance, they may not address critical issues

- Tendency is to follow checklist too closely - audit flows according to checklist not auditee response
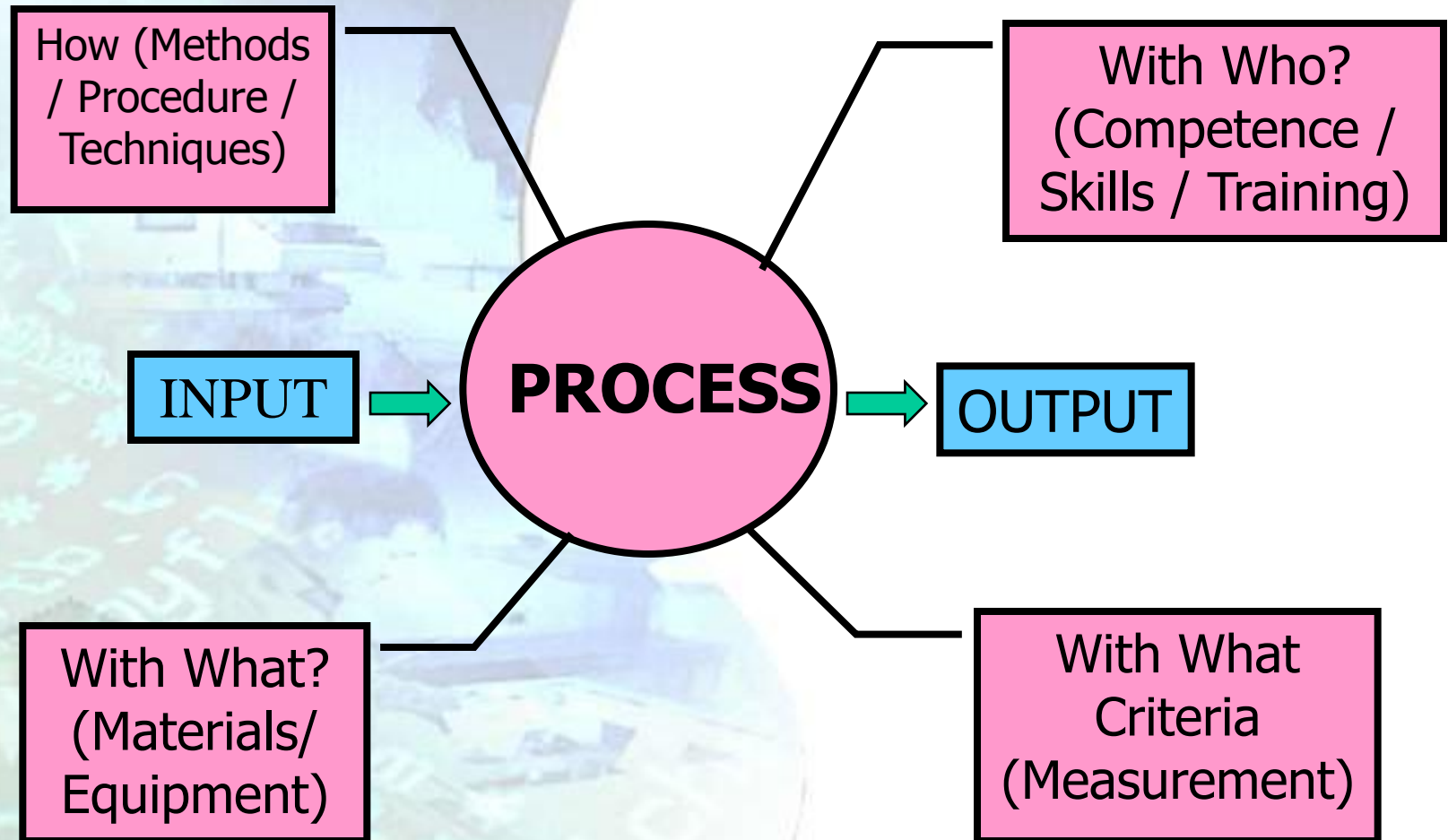
The purpose of checklist is as an aide-memoire. It is the servant not the master.

Audit objectives

Good questions - bring you closer to your objectives

Checklist questions

Poor questions - irrelevant topics

Process Analysis diagram (Turtle Diagram)

How (Methods / Procedure / Techniques)

With Who? (Competence / Skills / Training)

INPUT → PROCESS → OUTPUT

With What? (Materials/ Equipment)

With What Criteria (Measurement)

| ITEM	DETAILS
Process	Process name, process activities
Input	Material, documents, specification, schedule, output from processes, etc.
Output	Product, documents, records, plan, sample, prototype, etc.
How	Linked process control, procedures, methods, techniques, etc.
With What	Machine, test equipment, computer, software, safety equipment, tooling, environment, etc.
With Who	Skill, competency, responsibility, authority, etc.
Measurement	Process Efficiency/Effectiveness - Quality objectives, indicators, targets, improvements,

Workshop 1
Prepare AUDIT PLAN
Prepare AUDIT CHECKLIST

OBJECTIVE :
To provide participants with practice on preparing audit plan and audit checklist

Assume that your team has been assigned to perform the Annual Internal Audit. As part of the audit preparation, your team is required to

1. Prepare an audit plan

2. Checklist based on the assigned processes
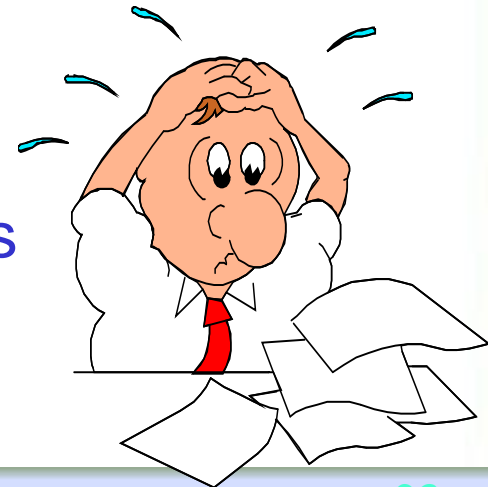
END OF SESSION 4: AUDIT PLANNING & PREPARATION

THANK YOU VERY MUCH