

Compliance Auditing

4th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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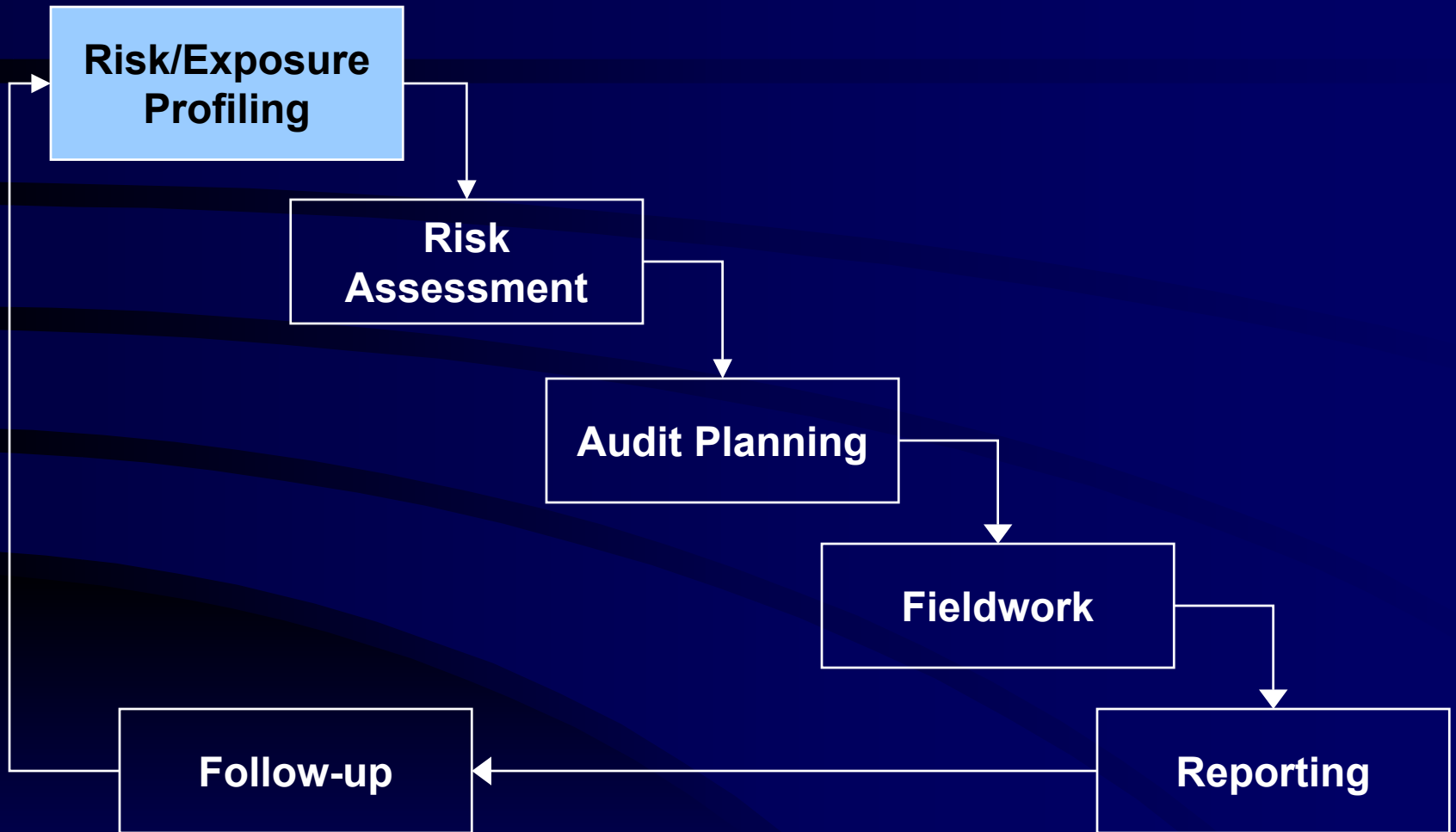
Auditing Discussion

- **Why** do an audit?
- **What** should you audit?
- **When** should you audit?
- **Who** should you audit?
- **Who** should do the audit?
- **How** do you do the audit?
- What are the **next steps**?

HOW

to go about conducting an
audit

Risk / Exposure Profiling



Managing Business Risk

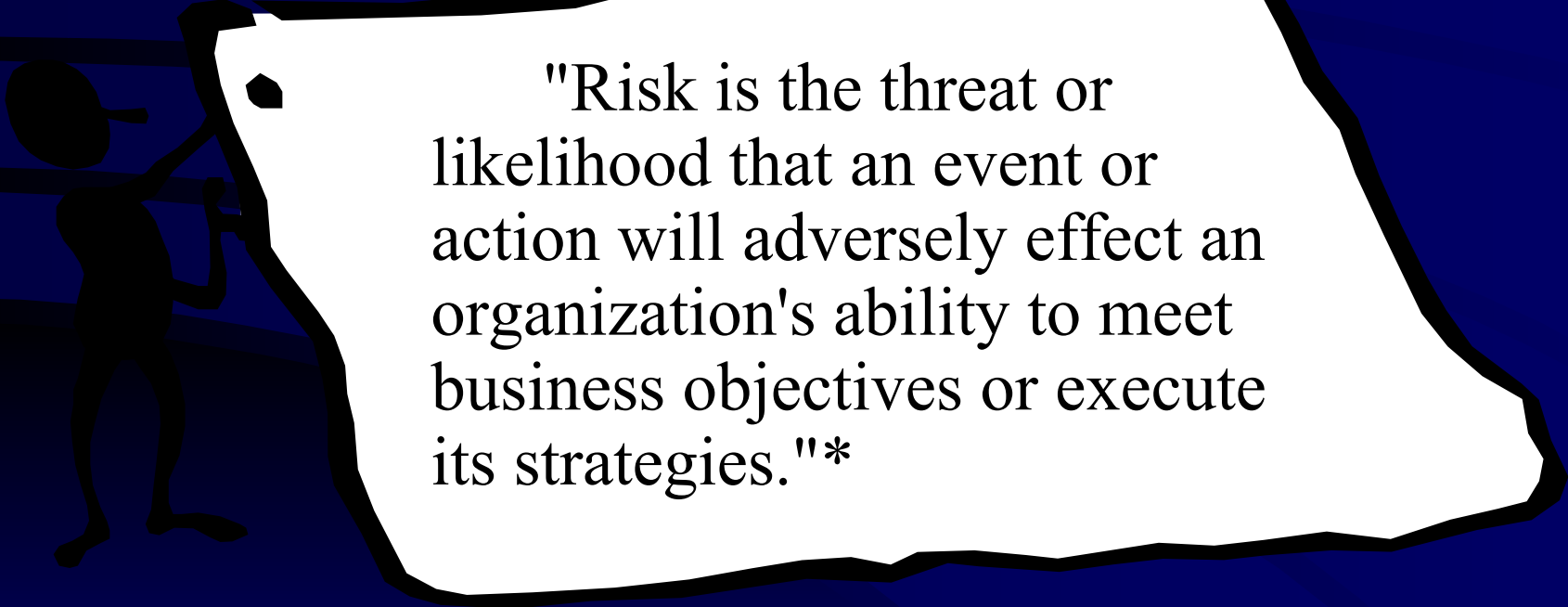
*What can go wrong with my
business?*

*If that something goes wrong,
Does it matter?*

*If it matters,
Can I avoid, monitor, or manage
it?*

Risk

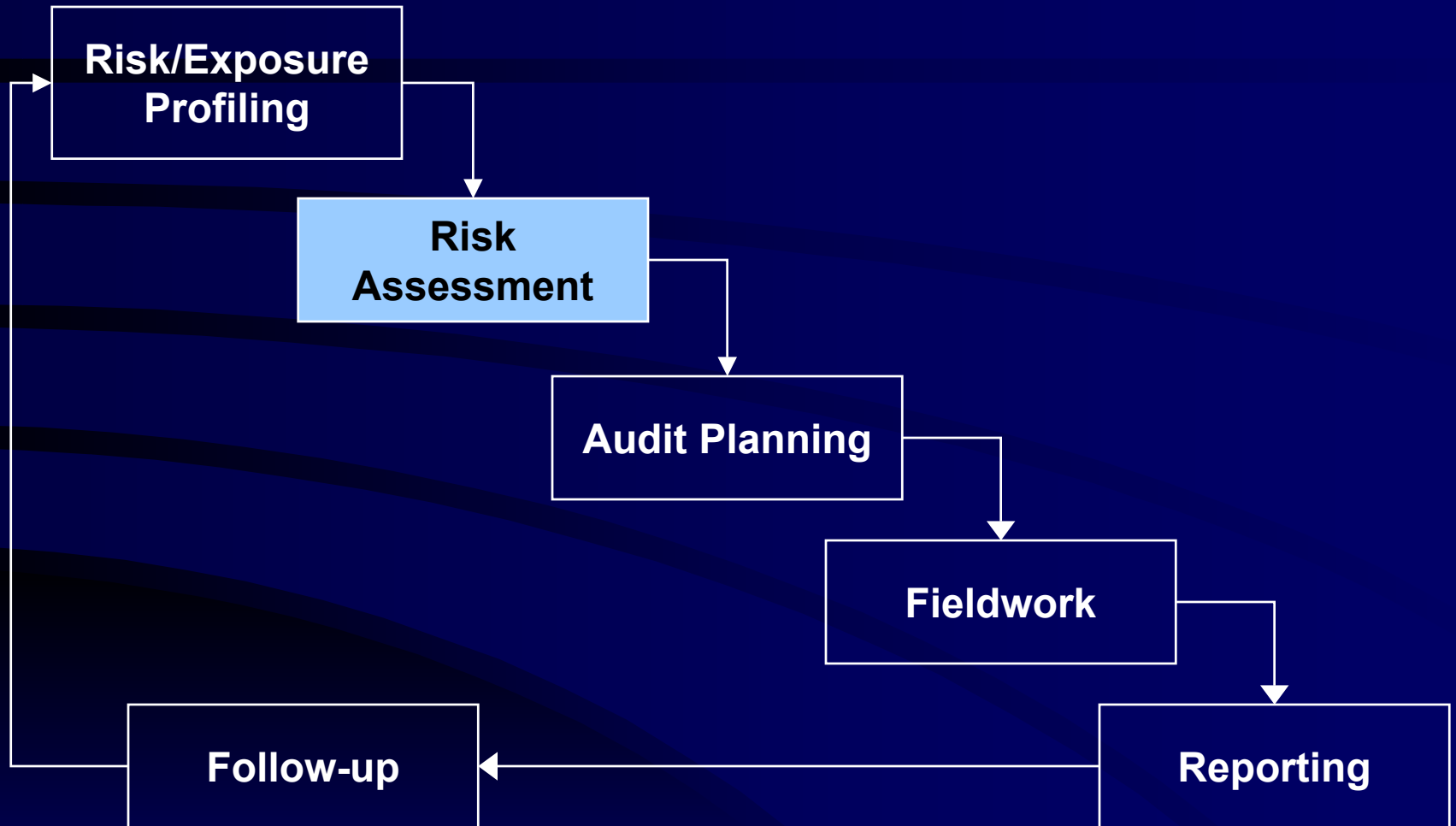
Risk Definition



"Risk is the threat or likelihood that an event or action will adversely effect an organization's ability to meet business objectives or execute its strategies."*

* *Managing Business Risk, An Integrated Approach, The Economist Intelligence Unit, 1995*

Risk Assessment



Why conduct a risk assessment?

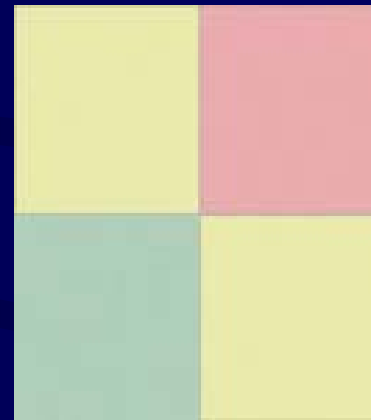
- To quantify and use a constant method by which compliance measures are assessed
- To identify those risk areas in the high risk potential and/or high risk consequence region that may require more resources to effectively implement and enforce policies
- To identify which areas of an effective compliance program are lacking across the corporation
 - Training and Education, Auditing and Monitoring
- To provide a starting point for to-be-created centralized compliance group

Risk Concepts

- ***Risk Driver***

- A risk driver increases or decreases the probability that a risk will occur

Impact



Probability



Risk Concepts

- *Risk Drivers*

- *Environmental Drivers:*

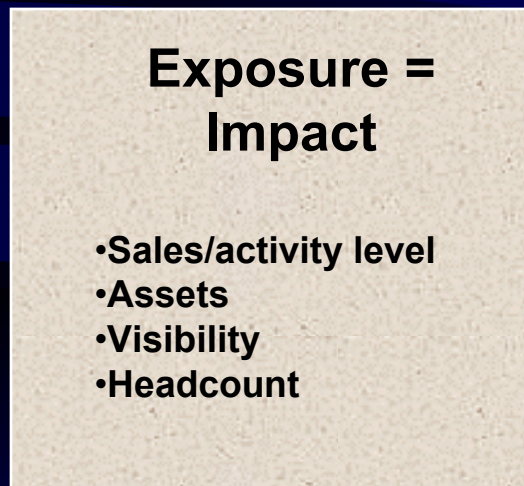
- External Environment
- Ethical Environment
- Control Environment

- *Operational Drivers:*

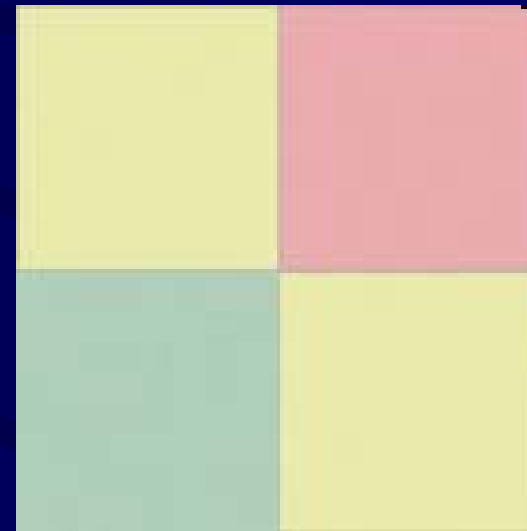
- Change
- Growth
- Business Complexity
- Pressure to Meet Goals

Risk Concepts

• *Exposure*



Impact



Probability

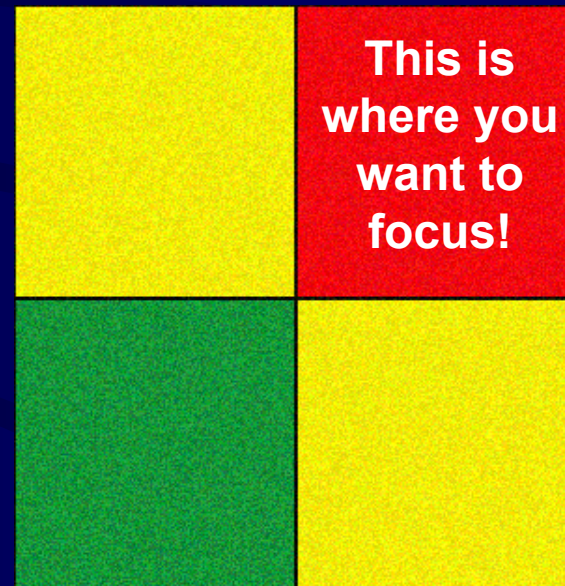
Do I care if something goes wrong?



Impact

High

Low



Low

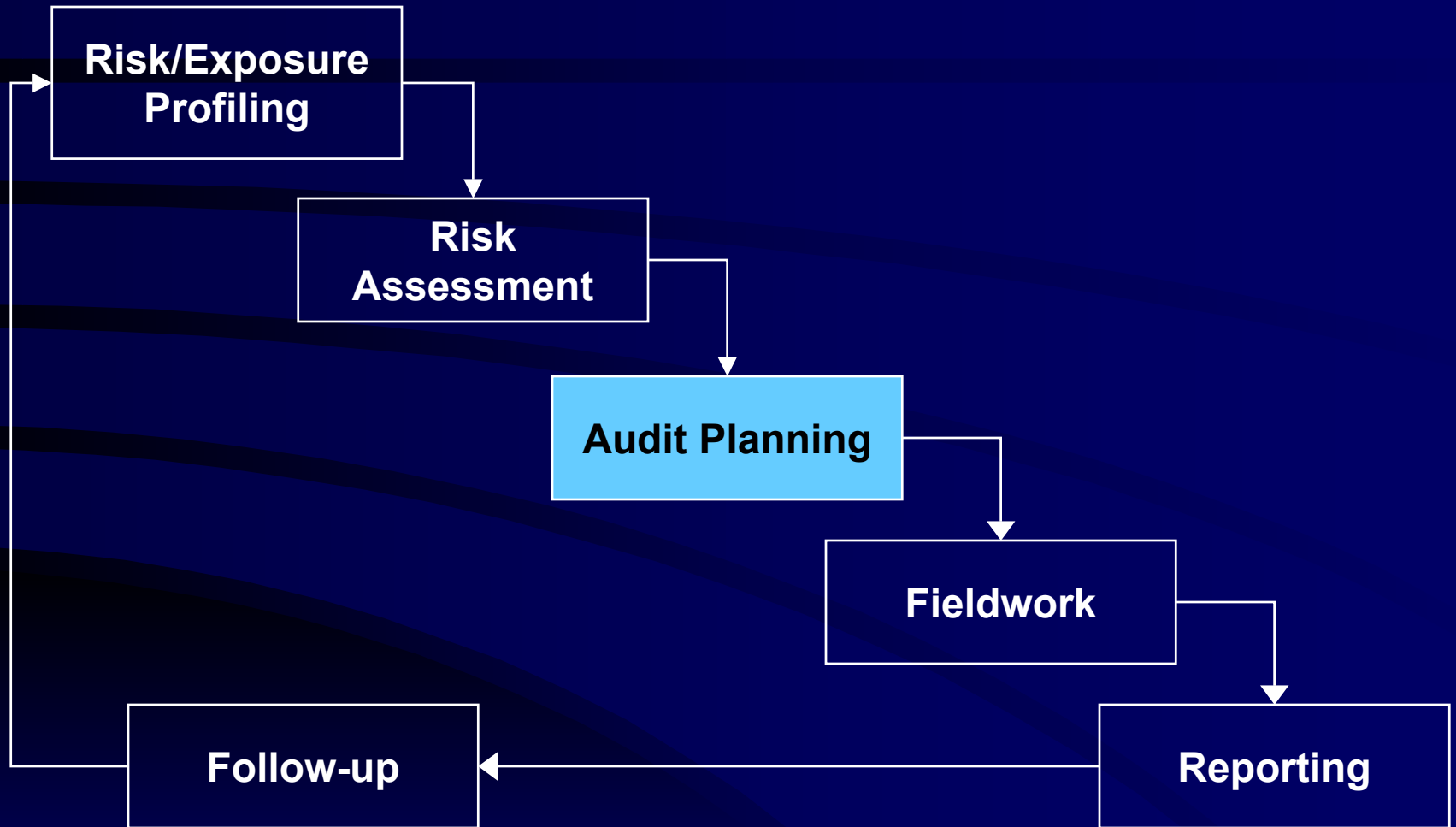
High

Probability

Risk Assessment Model

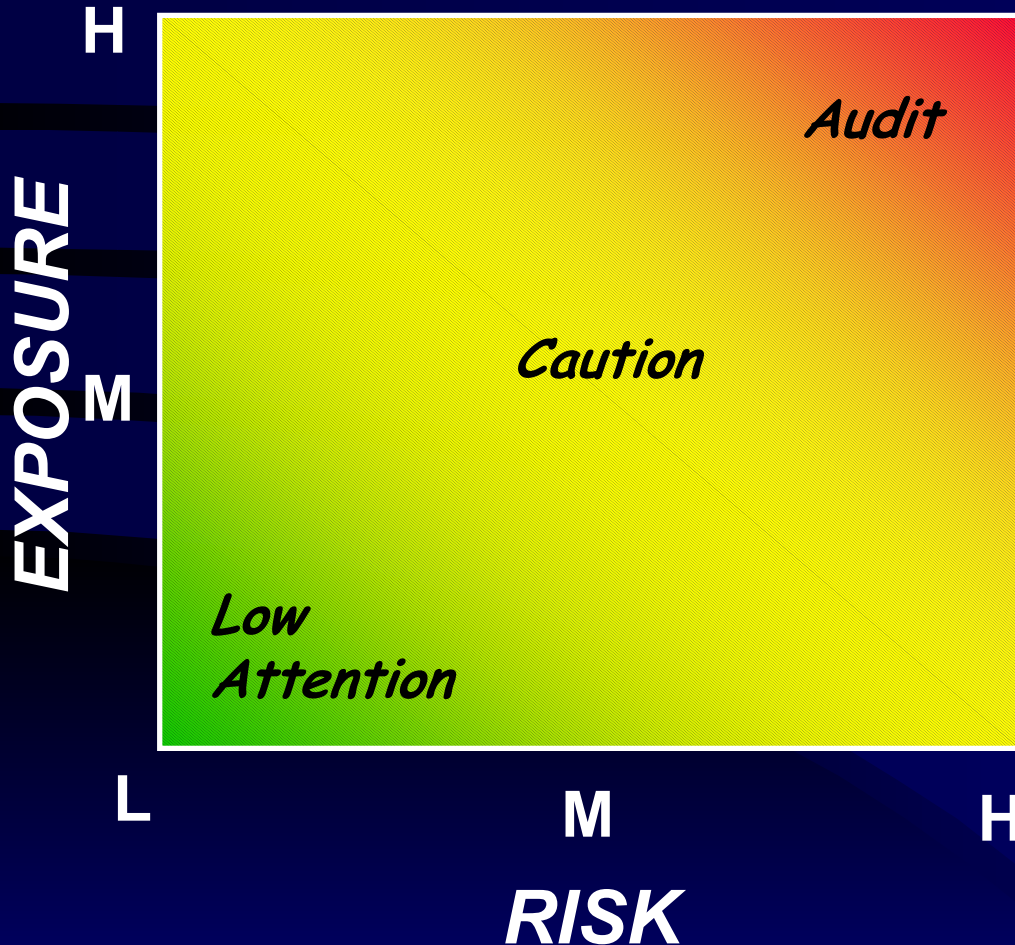


Audit Planning



Prioritize Audit Units

PLANNING GUIDELINES



Audit

Receives significant audit effort annually

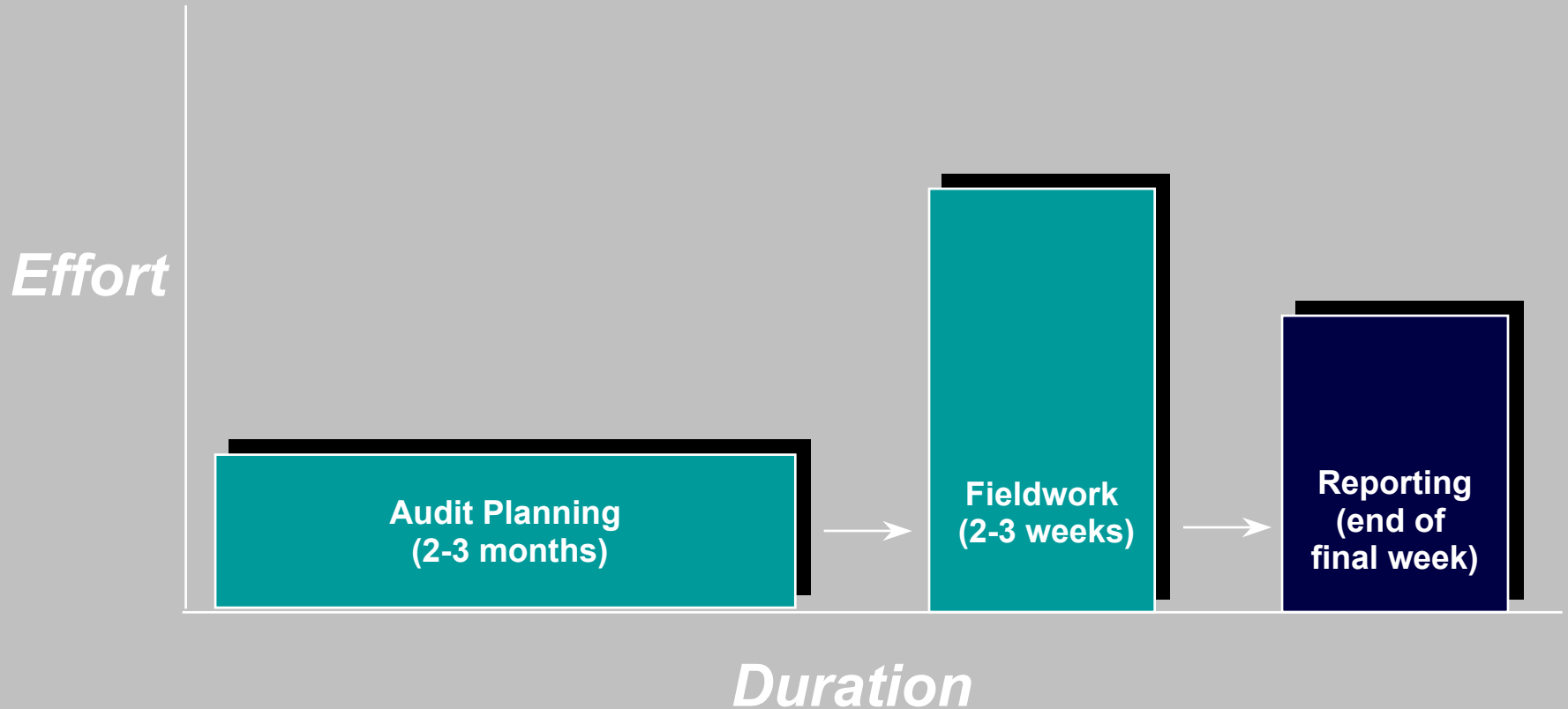
Caution

Audit activity based on specific risk factors

Low

No Audit Services activity current plan year

Audit Engagement Overview



Audit Process

"Auditor" Responsibilities

Interviews
Observations
Testing

Arrive on site



Validation
Feedback
Action Plans

Leave site

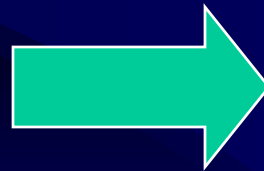
"Site" Responsibilities

Program Development

Program
1.
2.
3.
4. ...

- Outlines objectives for the audit
- Indicates what is to be done
- Describes how it is to be done
- Provides record of planned procedures
- Assists audit control

Compliance Audits



Written policies and procedures

Training

Auditing/monitoring

Discipline/learning

Population Selection and Data Collection

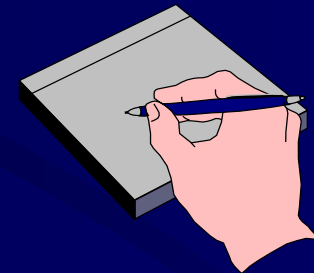
Determining Audit Population

- All
- Cumulative %
- Square root of $n + 1$

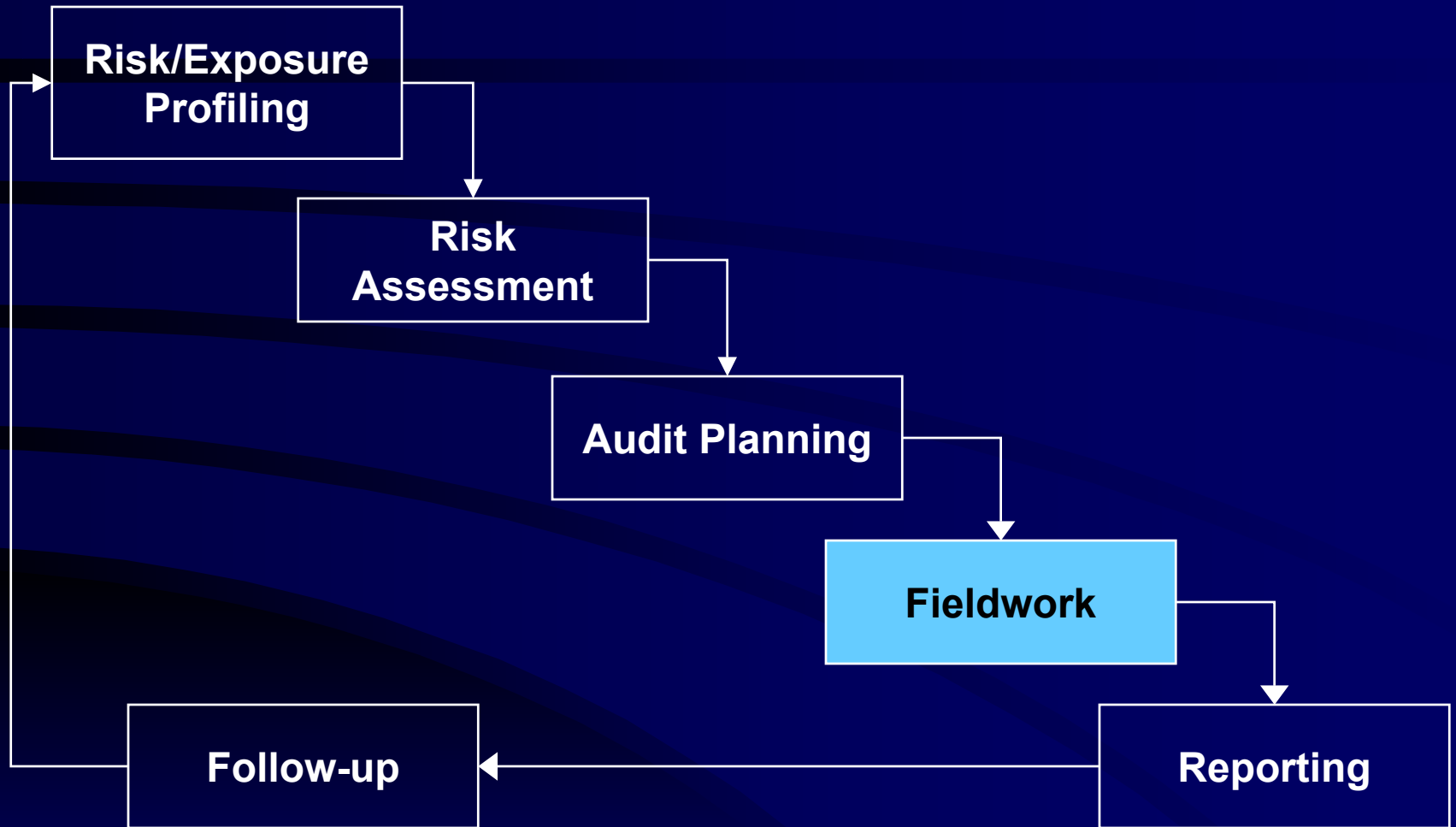


Data Collection

- Interview Questions
- Spreadsheets



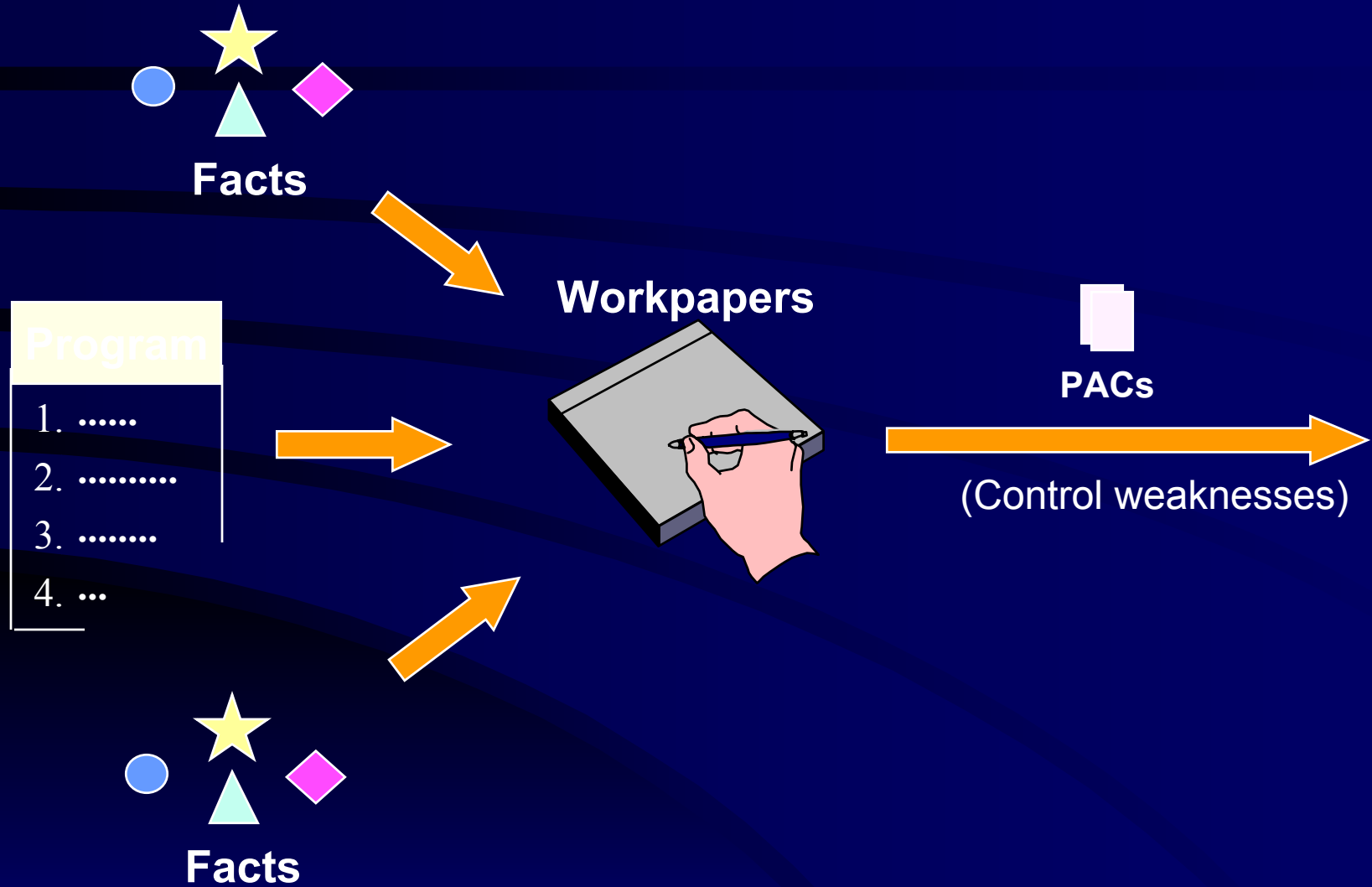
Fieldwork



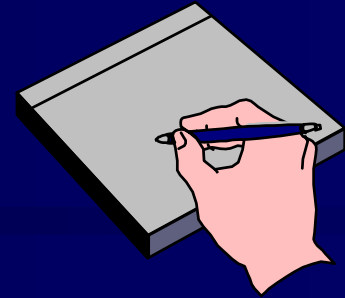
Fieldwork Process

- Opening Meeting (Audit Objectives and Scope)
- Gather information
 - Conduct interviews
 - Understand business processes
 - Review procedures and documentation
 - Perform testing and observations
- Document facts
- Review against control objectives
- Hold periodic "talk-ups" to validate facts
- Consolidate and assess results
- Write DRAFT report
- Closing Meeting (Distribute Final Report)

Documentation Process



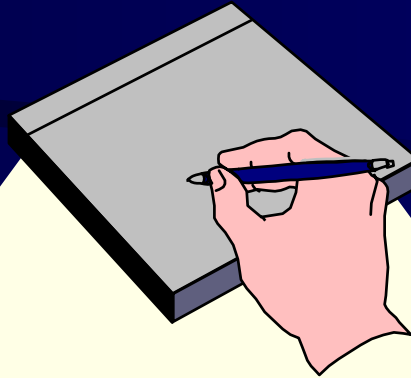
Workpapers



- **Workpapers document the audit**
- Prepared by auditor and reviewed by lead
- Standard format
- Clearly state nature and extent of work
- Record of information obtained, analyses made, findings, and conclusions
- Support for recommendations

Workpapers & Evidence

Workpapers are based on facts (Evidence)



★ **Observations**

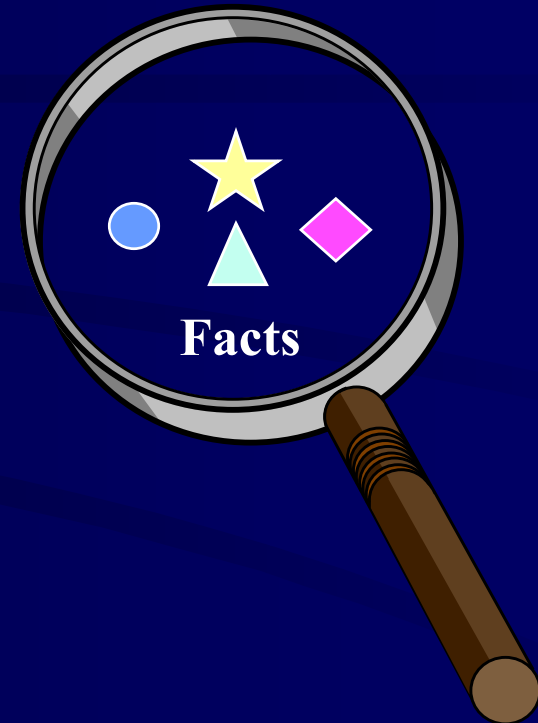
● **Review of Procedures,
Documentation**

◆ **Interviews**

▲ **Tests, Analytical Processes**

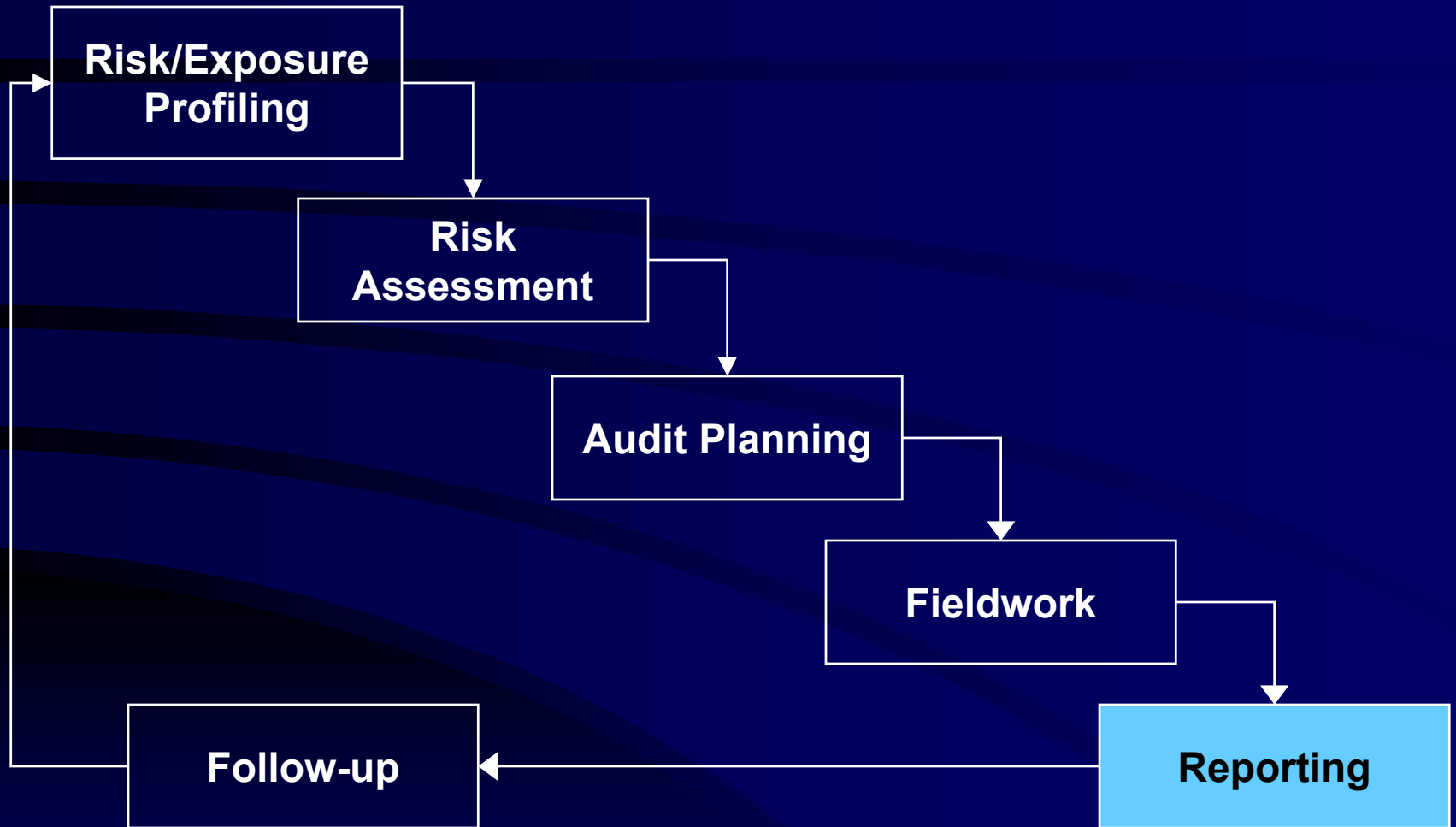
Evidence

- **Sufficient**
 - Convincing
 - Adequate detail
- **Relevant**
- **Competent**
 - Factual
 - Reliable
 - From best source (independent)
 - Consistent with other evidence

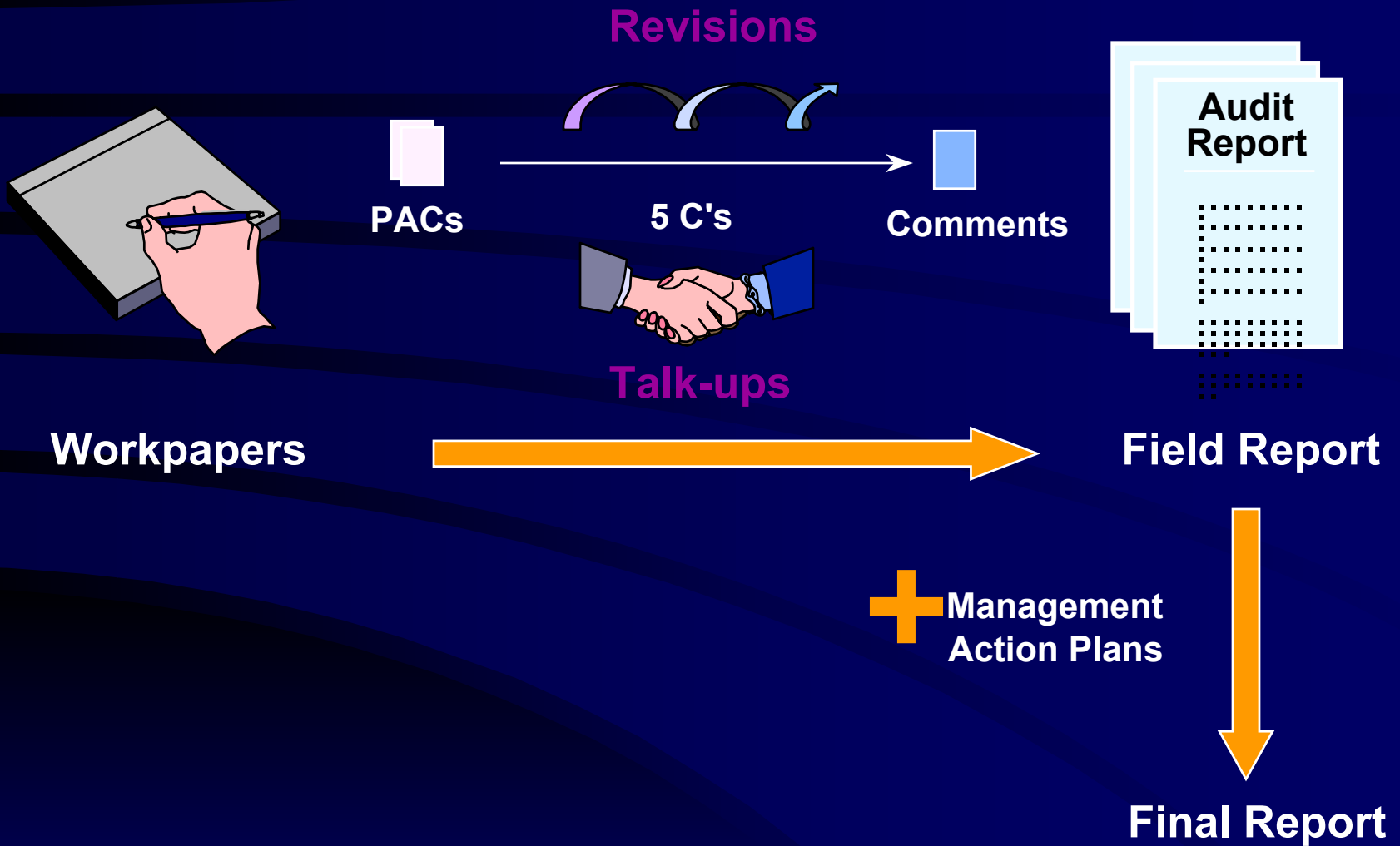


- Validity of audit evidence is a function of its source
- The more independent the source, the greater the value

Reporting



Reporting Process



Potential Audit Comments (PACs)






PACs

- Summarized audit findings
- Basis for developing comments
- Verify findings with auditee (talk-up)
- Link between workpapers and report
- Not all PACs are in the report

Report Comments

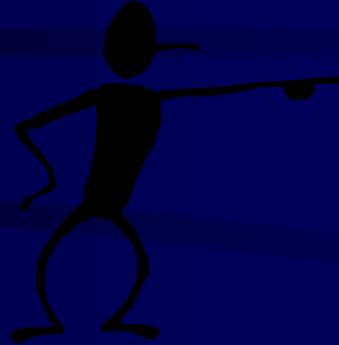
- Comments Should Not:

-  Describe detail auditing done
-  Document operating procedures
-  Educate readers about details of processes



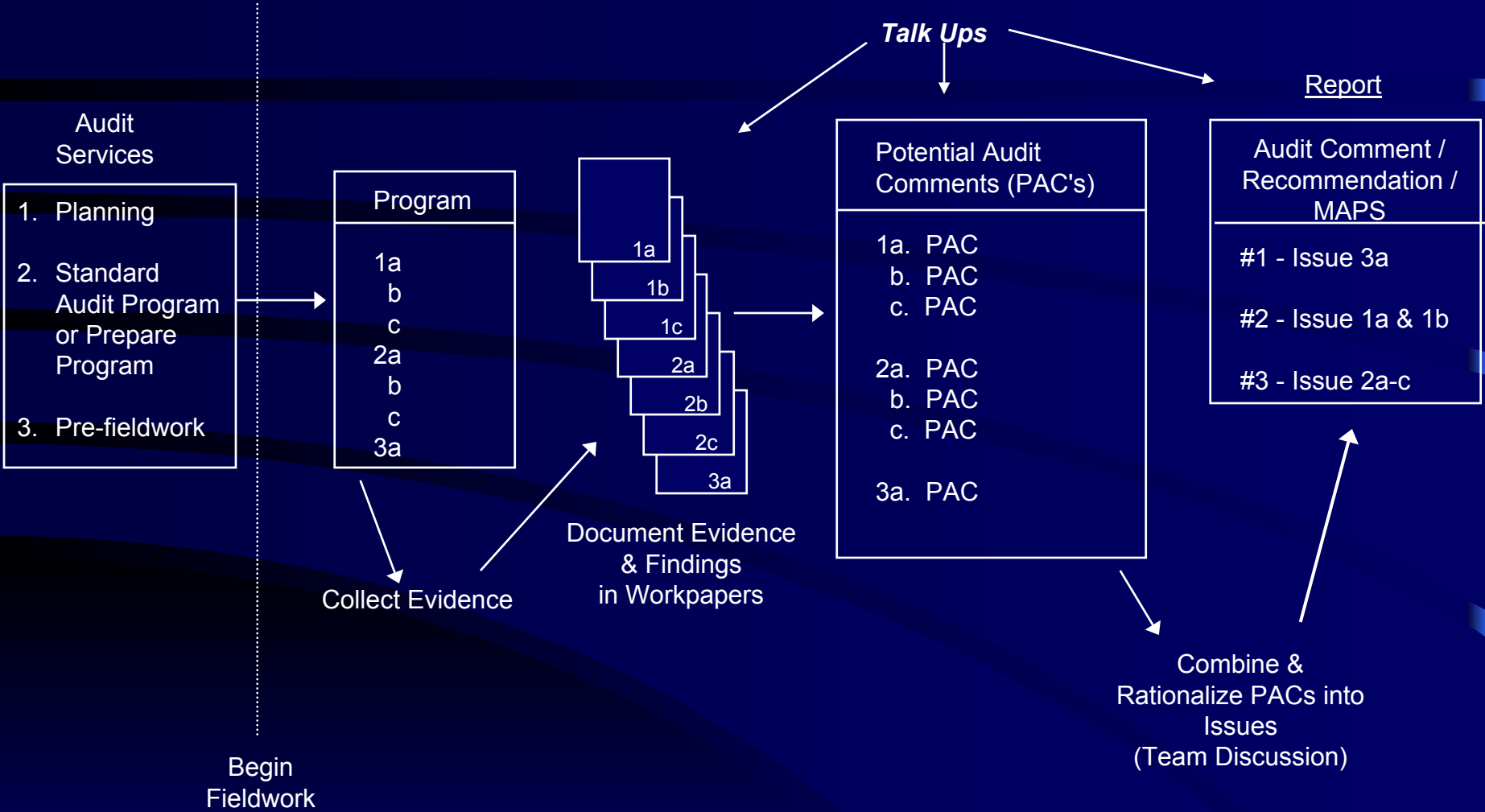
- ***The reader should know this data !***

Management Action Plans



- Auditees specify how and when they plan to address the condition described in each comment
- Signal to Audit Services that local management will address audit results

Audit Process



Final Report

Final Report Distribution:

MAP's



Detailed Comments

Comment 1

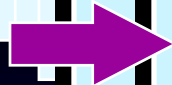
Recommendation

Management Action Plan

EXECUTIVE SUMMARY

- Objectives
- Risks & Exposures
- Overall Assessment
- Rating

Executive Summary



- Line Management
- Compliance Organization
- General Auditor
- Outside auditors
- HR
- **RED audits – who else?**

Rating Scale

GREEN

- Control environment is satisfactory.
- Continuing local management action and resource allocation is sufficient.
- Processes/policy/procedure/practice sufficient to meet business objectives

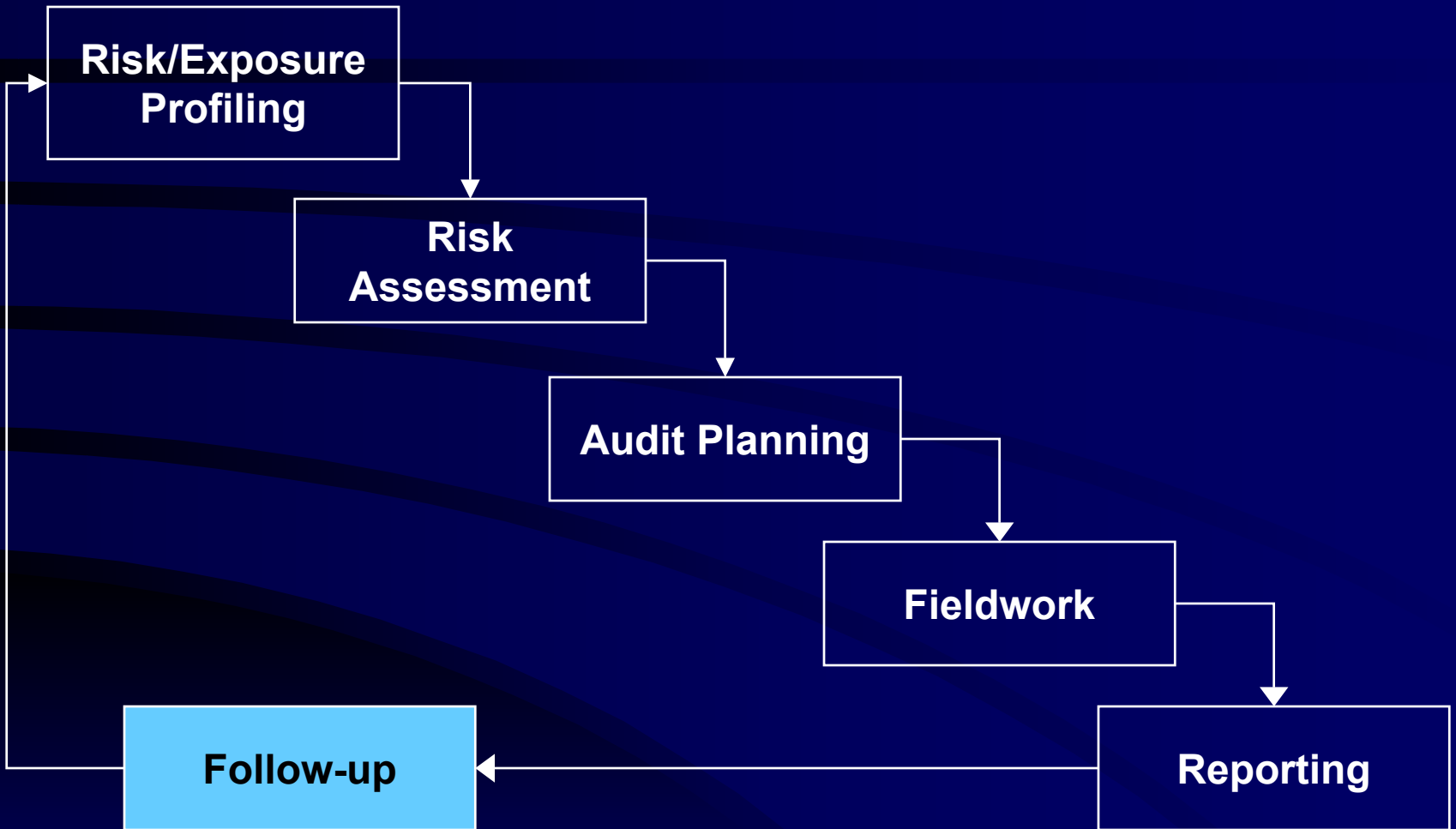
YELLOW

- Improvement required.
- Important business risk issues that justify management action, resource allocation.
- Processes/policy/procedure/practice in place but effectiveness needs to be enhanced.

RED

- Direct, immediate management action and resources required.
- Serious business risks present.
- Processes/policy/procedure/practice insufficient to give reasonable assurance of meeting business objectives.

Follow-up



Red Comment Follow-up

- Audit Services will follow-up on any **Red Comments** within 6 months of the audit
- The status of all **Red Comments** are reported to the Audit Committee as one of the following:
Implemented, Past Due, or Not Yet Due
- An item is identified as Past Due if the Affiliate fails to complete the Management Action Plan by the Implementation Date stated in the Final Report