



Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Student Guide

2014




GLOBAL BIORISK MANAGEMENT CURRICULUM

**Establishing Biorisk Management Goals,
Objectives, Roles & Responsibilities**

Welcome and Introductions




Welcome to Establishing Biorisk Management Goals,
Objectives, Roles & Responsibilities



Introductions

- Instructors
- Students
 - Your name?
 - Where are you from?



Slide 2

Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
<i>Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.</i>					
What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?		

Use space on back, if needed



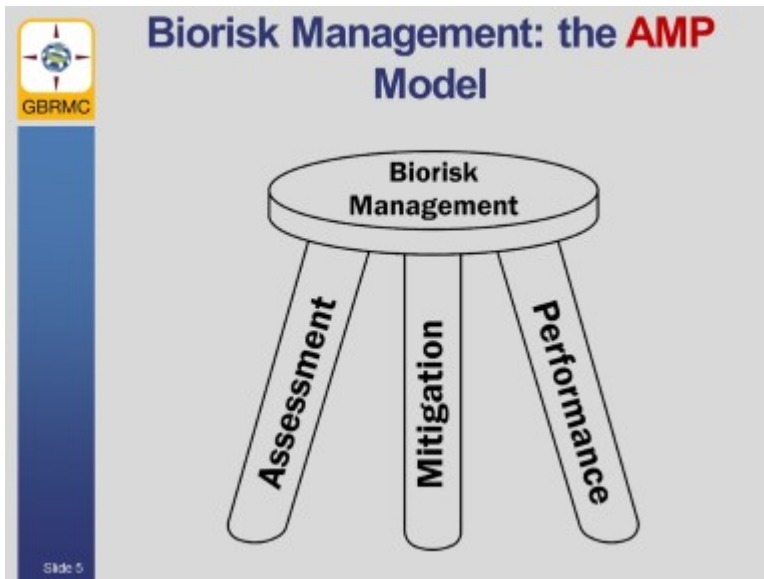
Key Messages

- While a policy states commitment and intent and the direction of a BRM program, goals provide a target.
- Objectives provide the steps to get there.
- In order to more effectively facilitate the execution of Biorisk management, roles and responsibilities must be established
- Not all goals can (or should be) pursued at the same time.
- Goals, objectives, roles and responsibilities must be communicated (transmitted and received) to "count"
- Goals, objectives, roles and responsibilities should be a living document and must reflect emerging issues and continuous improvement.

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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Biorisk Management



Record refresher notes on the AMP model and biorisk management.

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Biorisk Management



Key Components of Biorisk Management

- **Biorisk Assessment**
 - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable



Slide 6

Define Biorisk Assessment:



Key Components of Biorisk Management

- **Biorisk Mitigation**
 - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



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Define Biorisk Mitigation:

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Biorisk Management



Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



Define Performance:

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Policy, Goal, Objective?



What is the Difference Between. . .

Group Exercise:

- A **policy**,
- A **goal**, and
- An **objective**?
- Sometimes these words are used interchangeably.

In your groups, please spend **5 minutes** to discuss how they are the **same** and how they **differ**. Write your answers in your **workbook**.

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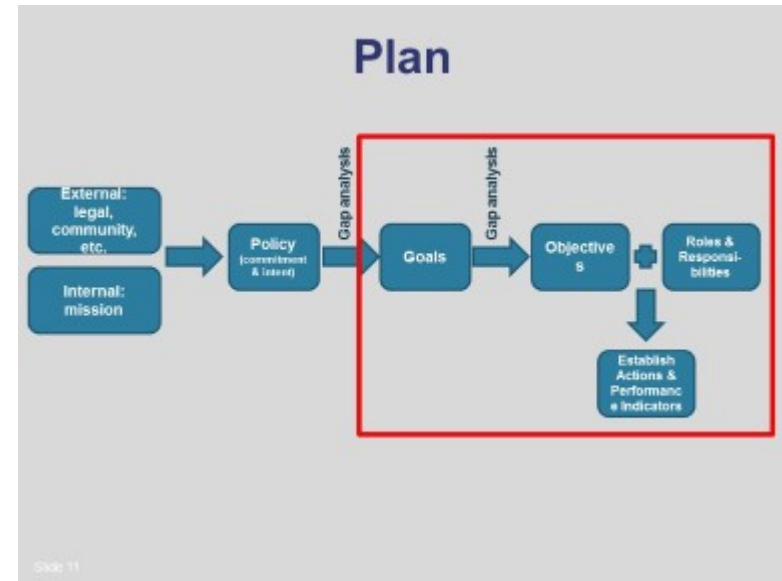
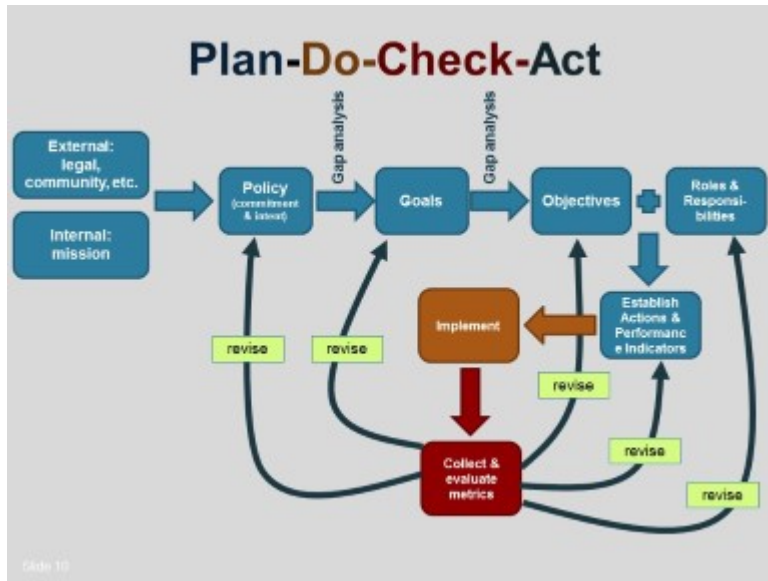
What are the similarities?

What are the differences?

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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

PDCA




Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

PDCA



How does the PDCA cycle help define policy, goal, and objectives?


Notes:



CWA 15793:2011

4.3.3.1 Biorisk Control Objectives and Targets

- The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.



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Goal or Objective?

What is the difference between a goal and an objective?



Setting Goals & Objectives

What is the difference between a goal and an objective?

- **Goal** (an observable and measurable end result)
 - We want to aim our resources and efforts towards this **outcome**
- **Objectives**
 - These are the steps we need to take, in a more or less fixed timeframe, to **move towards** and achieve the outcome

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**CWA 15793:2011
A Good Starting Place for GOALS**

4.4.4 Operational control

- 4.4.4.1 General safety
- 4.4.4.2 Biological agents and toxin inventory and information
- 4.4.4.3 Work programme, planning and capacity
- 4.4.4.4 Change management
- 4.4.4.5 Work practices, decontamination and personnel protection
 - 4.4.4.5.1 Good microbiological technique
 - 4.4.4.5.2 Inactivation of biological agents and toxins
 - 4.4.4.5.3 Waste Management**
 - 4.4.4.5.4 Clothing and Personal Protective Equipment (PPE)
- 4.4.4.6 Worker health programme
 - 4.4.4.6.1 Vaccination of personnel

- 4.4.4.7 Behavioral factors and control of workers
 - 4.4.4.7.1 Personnel reliability
 - 4.4.4.7.2 Contractors, visitors and suppliers
 - 4.4.4.7.3 Exclusion
- 4.4.4.8 Infrastructure and operational management
 - 4.4.4.8.1 Planning, design and verification
 - 4.4.4.8.2 Commissioning and decommissioning
 - 4.4.4.8.3 Maintenance, control, calibration, certification and validation
 - 4.4.4.8.4 Physical security
 - 4.4.4.8.5 Information security
 - 4.4.4.8.6 Control of supplies
- 4.4.4.9 Transport of biological agents and toxins
- 4.4.4.10 Personal security

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CWA 15793:2011 - 4.4.4.5.3

4.4.4.5.3 Waste Management


- The organization shall **establish** and **maintain** an appropriate waste management policy for biological agents and toxins.
 - *Why does a waste management **policy** need to be established?*
 - *What is “**appropriate waste management**”?*
 - *What are the **steps** to assuring appropriate waste management?*

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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

CWA


Notes:

 **CWA 16393:2012 - Guidance**

To ensure that waste is properly managed and disposed of in a safe, efficient and cost effective manner and to ensure any biological waste which may have additional hazards (e.g. radioactivity) is investigated, considered, and addressed.

– Identify:

- roles and responsibilities;
- nature of the waste (e.g. liquid or solid waste);
- the appropriate decontamination processes; and
- local and environmental waste management policies.



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**Establishing Biorisk Management Goals,
Objectives, Roles & Responsibilities**

SMART

Notes:



SMART Objectives

- **S**pecific
- **M**easurable
- **A**ttainable
- **R**easonable
- **T**ime-based

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Goals & Objectives

Exercise:

- **Policy:** Biological agents and toxins are disposed and/or destroyed appropriately
- **Goal:** Establish a waste management policy to assure that biological agents and toxins are appropriately disposed and/or destroyed.
- **Objectives?** "SMART" ways to move towards the goal

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Goals & Objectives

Exercise:

"SMART" objectives to move towards the goal

- Step 1. **Ask questions to gather information.**

For example:

- Find out how biological agents and toxins can be disposed or destroyed.
- Find out how to determine what methods are "appropriate"

- Step 2. **Shape these questions into SMART tasks.** For example:

- "In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials."
- "In Month 2, using the results of the survey, create a list of the types of waste and the biological agents and toxins likely contained in each type of material."

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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Roles and Responsibilities

How do all these components fit together?



Roles & Responsibilities (R&R)

- You have your target (**goal**).
- You have your arrows (**objectives**).
- Now, you need an archer to direct the arrow towards the target. (**Role**)
- And instructions on how to direct the arrow (**Responsibilities**)



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Why are R&R Important?

Exercise:

What are the **consequences** of **NOT** establishing **roles & responsibilities**?

In your group, take **5 minutes** to list 3 to 5 consequences of NOT establishing roles & responsibilities. Write these in your **workbook**.

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What are the consequences of not establishing roles and responsibilities?

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Roles and Responsibilities



What are Challenges in Establishing R&R?

Discussion:

- What kinds of **obstacles** might keep you from establishing roles & responsibilities?
- What **steps** can you take to **overcome** these challenges?

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What are some challenges to establishing roles and responsibilities?

How can they be overcome?

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Roles and Responsibilities



What Roles Impact Biorisk Management?

Question:

What roles impact or influence biorisk management?

As a group, take **5 minutes** to brainstorm all the roles **within a facility** that can impact or influence biorisk management. Write each role on a separate sticky note.

Take another **5 minutes** to brainstorm all the roles **outside of a facility** that can impact or influence biorisk management. Write each role on a separate sticky note.

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What roles impact or influence biorisk management?

Within a facility:

Outside a facility:



What Roles Impact Waste Management?

Question:

Which of these roles impact or influence waste management?

As a group, look at your answers for the roles that impact biorisk management. Determine which of these roles impact or influence **waste management in a bioscience facility**.

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Which of these roles impact or influence waste management?



Determining Responsibility

- Before writing specific responsibilities, it can be helpful to determine the **basic level of responsibility**.
- One model for levels of responsibility:
 - Decision
 - Involved
 - Consulted
 - Informed
 - Not Informed



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Determining Responsibility

- **Decision** – The ultimate decision-maker who is accountable for the objective. **Only 1 per objective.**
- **Involved** – Actively contributes to and shapes the actions to accomplish the objective.
- **Consulted** – Possesses and contributes key information while the actions for accomplishing the objectives are being determined
- **Informed** – Must be aware of and, possibly perform, an action, but who is not involved in shaping the action.
- **Not Informed** – No role in the action or objective.

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One Tool for Determining Responsibilities

<i>Objective</i>	Top Mgmt	Lab Mgmt	Biosafety Professional	Worker
In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials.”				
In Month 2, using the results of the survey, create a list of the types of waste and the biological agents and toxins likely contained in each type of material.”				
Objective 3. . .				
Objective 4. . .				
A= Decision B = Involved C = Consulted D = Informed E = Not Informed				

Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Actions



Actions

- **Actions** are specific responsibilities for each role to accomplish an objective.
- Actions must be **SMART**.

By [this time], [this role] must do [this action] using [these steps] and reporting it [this way] to [this role].


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Why must actions be SMART?

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Actions

Write one SMART action for one role related to the objective:



Create an Action

Exercise:


Objective: In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials.

- Look at the Responsibility Level chart you just completed.
- Write one SMART action for one role related to the objective above.

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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Goals



Goals

Group Exercise Step 1:

In your groups, please spend **5 minutes** to choose one topic from CWA 15793:2011 4.4.4. (slide#11) and **write a goal** for that topic.


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Write a goal using a topic from the CWA:

**Establishing Biorisk Management Goals,
Objectives, Roles & Responsibilities**

SMART

Write 3 – 5 SMART objectives:



SMART Objectives

Group Exercise Step 2:
In your groups, please spend **15 minutes** to write 3 to 5 **SMART objectives** for that goal.

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Roles



Roles

Group Exercise Step 3:

In your groups, please spend **10 minutes** to list the **roles** that influence or impact each objective.

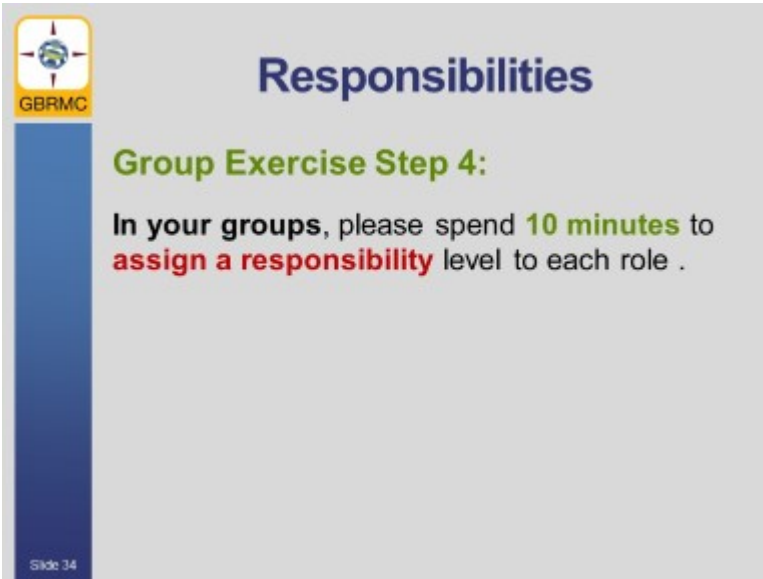
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List the roles that influence or impact each objective?

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Responsibly

Assign a responsibility level to each role.



Responsibilities

Group Exercise Step 4:

In your groups, please spend **10 minutes** to **assign a responsibility** level to each role .

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Tool for Determining Responsibilities

Goal:

	Roles			
<i>Objectives</i>				

A = Decision B = Involved C = Consulted D = Informed E = Not Informed

**Establishing Biorisk Management Goals,
Objectives, Roles & Responsibilities**

Action



SMART Responsibilities

Group Exercise Step 5:

In your groups, please spend **10 minutes** to write a specific, **SMART** responsibility (**action**) for one objective for each role with an assigned responsibility level.

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Write a specific SMART responsibility (action) for one objective, for each role with an assigned responsibility level:

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Tool for Determining Responsibilities

Goal:

Objective:

Role:

SMART Action to be taken by that role

Role:	SMART Action to be taken by that role



Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Goals



Prioritizing Goals & Objectives

Discussion:

Not all **goals** & **objectives** can be pursued at the same time.

- What are some **reasons** that would keep a goal from being addressed?
- What are some of the **factors** that influence the priority by which goals are addressed?

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What are some reasons that would keep a goal from being addressed?

What are some factors that influence the priority by which goals are addressed?



Priority Assessment

Assessing the consequences of NOT addressing a goal and the likelihood that those consequences would occur is a type of **risk assessment**.

A biosafety or biosecurity risk assessment feeds into this type of priority assessment.

For example, if a biosafety risk assessment reveals that a pathogen is likely to be spread via untreated waste, then the goal of establishing a waste management policy and program may receive high priority.



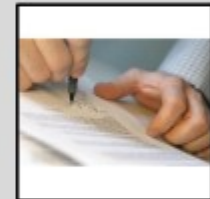
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Priority Assessment, continued

It may be acceptable to **DO NOTHING**, if the biorisk and priority assessments show that taking **NO** action would **not raise the risk**.

The **biorisk management system** approach requires that this decision-making process be **documented**.



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Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Communication



Communication

Group Exercise:

What happens if **goals, objectives, roles, and responsibilities** are not **communicated**?

In your group, take **5 minutes** to list **3 to 5 actions** for effectively communicating goals, objectives, roles, and responsibilities.

Discuss steps to take to be sure that these have been communicated.

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What happens if goals, objectives, roles, and responsibilities are not communicated?

List 3 – 5 actions for effectively communicating goals, objectives, roles and responsibilities.

What are the steps to make sure that these have been communicated?



Review and Revision

Discussion:

Goals & objectives will change over time.

- What are some **reasons** that they will change?
- How do you know when it is time to **review** and, possibly, **revise** goals & objectives?
- What **steps** should you take to review and revise goals, objectives, roles, and responsibilities?

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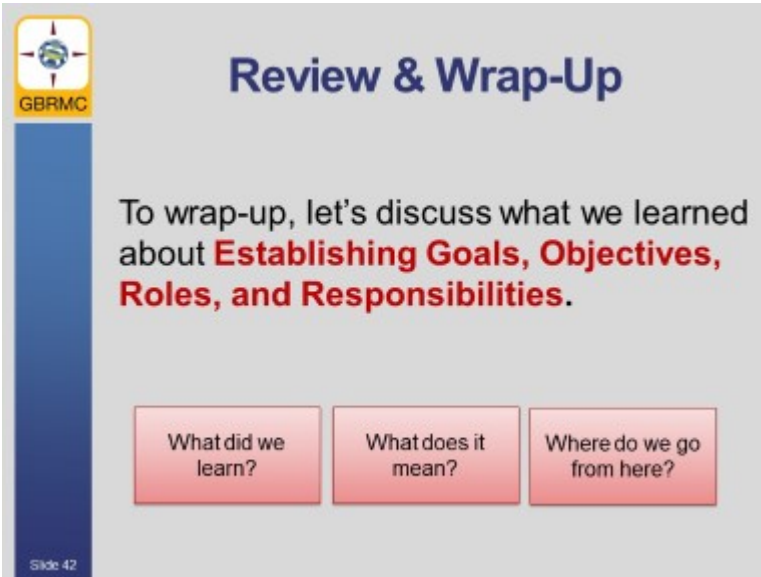
Why would goals and objectives change?

Notes:

Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities

Review

Notes:



Review & Wrap-Up

To wrap-up, let's discuss what we learned about **Establishing Goals, Objectives, Roles, and Responsibilities.**

What did we learn? What does it mean? Where do we go from here?

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Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
------	--	------	--	---------------	--

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed