Risk Based Environmental Management System (EMS) Auditing

Presented by:
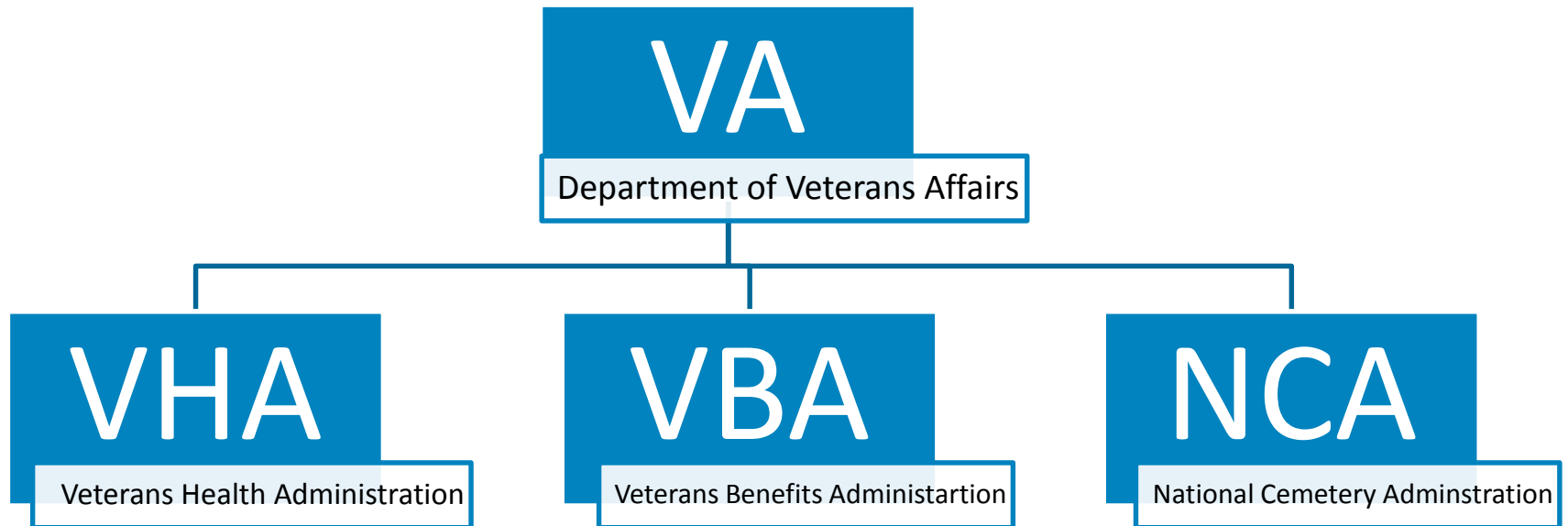
Jody McClarin

VHA National Green Environmental Management Systems Program Manager for Operations

October 2019

VA HEALTH CARE | Defining **EXCELLENCE** in the 21st Century

Veterans Health Administration

Outline

- Welcome
- Basic EMS requirements at Federal Facilities
- EMS 101 and ISO 14001 2004 vs. 2015
- EMS Auditing Based on Compliance Auditing Data
- Using Focus Areas to Establish the Scope of your Audit
- Developing the Checklist and Criteria Statements
- Auditing for Conformance to Local Procedures
- Conclusion

Welcome

VA
Department of Veterans Affairs

VHA
Veterans Health Administration

VBA
Veterans Benefits Administartion

NCA
National Cemetery Adminstration

Department of Veterans Affairs Environmental Programs

VA » Office of Asset Enterprise Management

Office of Asset Enterprise Management

VA Energy Management Program Service

VA's Energy Management Program Service is focused on achieving cost savings and improving energy and water infrastructure.

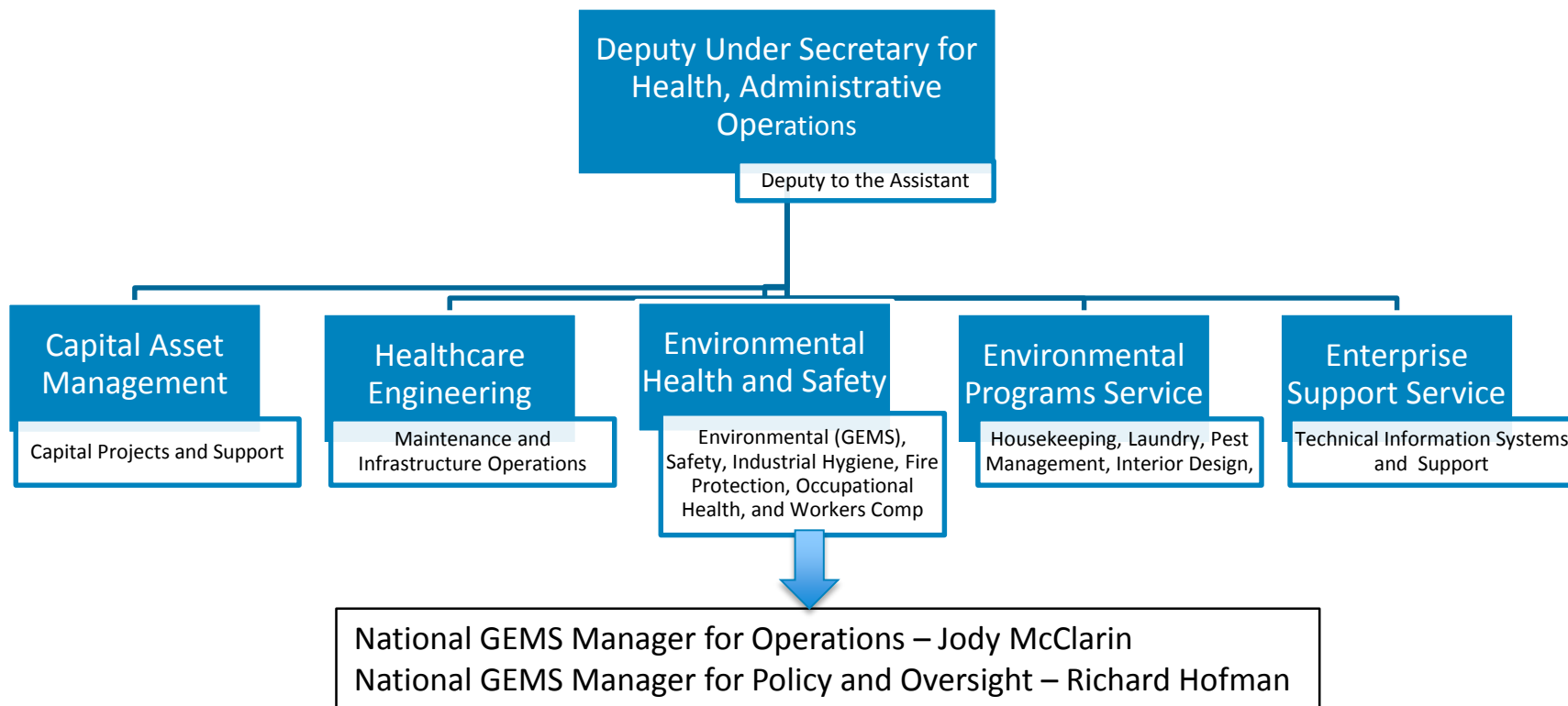Find out how we're doing »

VA Energy Management Program Service (EMPS)

Enhanced-Use Lease Program (EUL)

Strategic Capital Investment Plan

https://www.energy.va.gov/index.asp

Veterans Health Administration Environmental Programs

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Deputy Under Secretary for
Health, Administrative
Operations
    Deputy to the Assistant
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Capital Asset Management
Capital Projects and Support

Healthcare Engineering
Maintenance and Infrastructure Operations

Environmental Health and Safety
Environmental (GEMS), Safety, Industrial Hygiene, Fire Protection, Occupational Health, and Workers Comp

Environmental Programs Service
Housekeeping, Laundry, Pest Management, Interior Design,

Enterprise Support Service
Technical Information Systems and Support

National GEMS Manager for Operations – Jody McClarin
National GEMS Manager for Policy and Oversight – Richard Hofman

Basic EMS requirements at Federal Facilities

- Executive Orders requiring EMS at Federal Agencies
  - 2000 – EO 13149, Greening the Government Through Federal Fleet and Transportation Efficiency (required EMS at all appropriate facilities by 2005, any format)
  - 2007 - EO 13423, Strengthening Federal Environmental, Energy and Transportation Management (required more widespread use, ISO 14001)
  - 2009 - EO 13514, Federal Leadership in Environmental, Energy and Economic Performance (Continue implementation of existing EMS programs)

- VA will continue to have an EMS at each Appropriate Facility
  - GEMS Managers hired to implement EO 13149
  - No 14001 Certification, but will use the basic elements
  - GEMS Managers Role is to develop custom programs

EMS 101 and ISO 14001 2004 vs. 2015

- What is an Environmental Management System?
  - Plan, Do, Check, Act
  - EPA Guide to Developing an EMS
- ISO 14001 Structure and Basics
  - 2004 vs. 2015 changes
  - Key Terms and Definitions
  - Elements in 14001 (2015)
    - Chapter 1: Scope
    - Chapter 2: References
    - Chapter 3: Terms and Definitions
    - Chapter 4: Context of the Organization
    - Chapter 5: Leadership
    - Chapter 6: Planning
    - Chapter 7: Support
    - Chapter 8: Operation
    - Chapter 9: Performance Evaluation
    - Chapter 10: Improvement

EMS 101
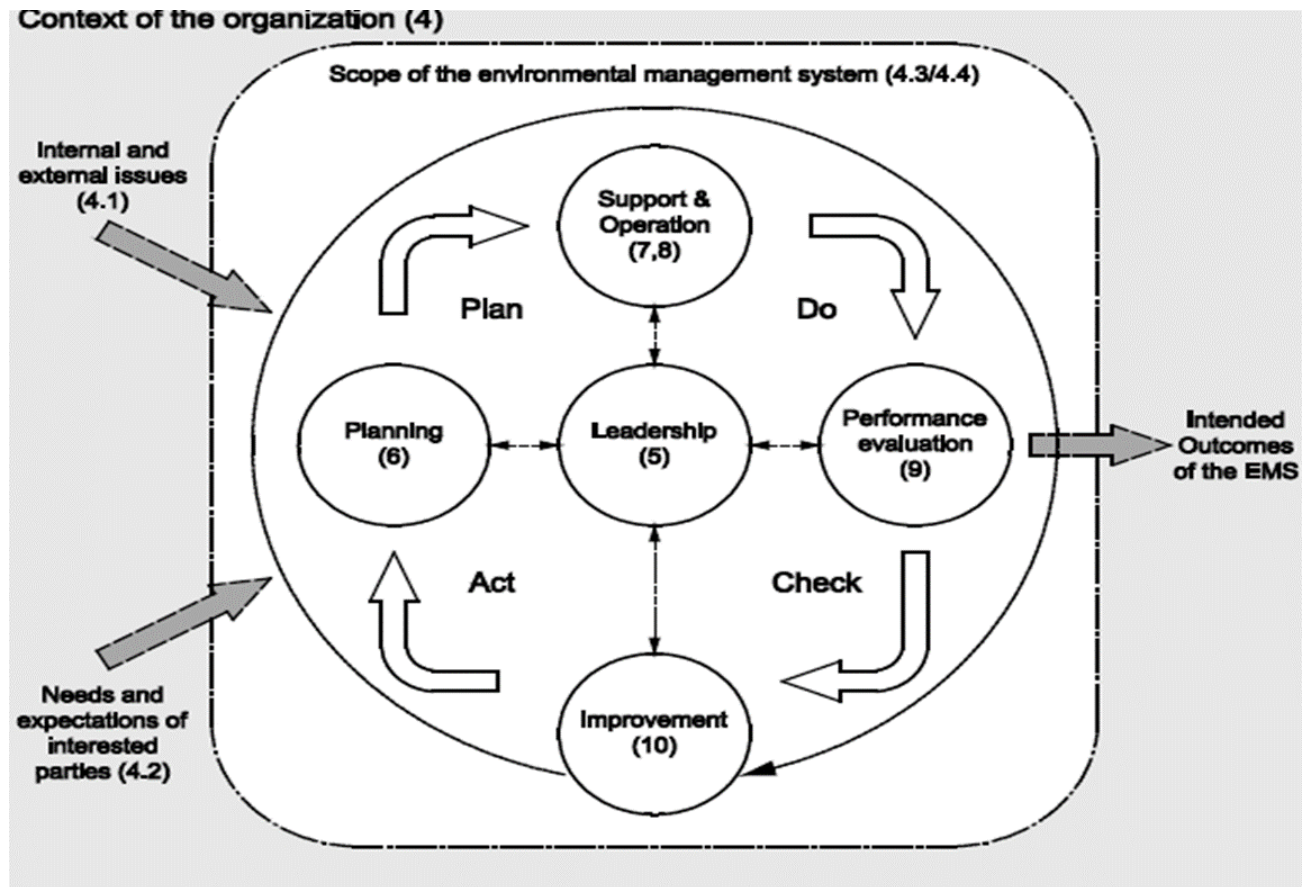
Note: Numbers in brackets refer to the clauses in this International Standard.

EPA Guide to Developing an EMS

https://www.epa.gov/ems/guide-developing-environmental-management-system-plan

PLAN

Plan: Planning, including identifying environmental aspects and establishing goals

- Step 1: Define Organization's Goals for EMS
- Step 2: Secure Top Management Commitment
- Step 3: Select An EMS Champion
- Step 4: Build An Implementation Team
- Step 5: Hold Kick-Off Meeting
- Step 6: Conduct Preliminary Review
- Step 7: Prepare Budget and Schedule
- Step 8: Secure Resources, Assistance
- Step 9: Involve Employees
- Step 10: Monitor and Communicate Progress

DO

Do: Implementing, including training and operational controls

- Step 1: Identify Legal and Other Requirements
- Step 2: Identify Environmental Aspects and Related Products, Operations, and Activities
- Step 3: Define Views of Interested Parties
- Step 4: Prepare Environmental Policy
- Step 5: Define Key Roles and Responsibilities
- Step 6: Establish Objectives and Targets
- Step 7: Develop Environmental Management Programs, Identify Operational Controls, and the Identify Monitoring and Measurement Needs
- Step 8: Establish Corrective Action, Document Control, and Records Management Processes
- Step 9: Establish Operational Controls and Monitoring Processes
- Step 10: Define Job-Specific Roles and Responsibilities
- Step 11: Plan and Conduct Initial Employee Awareness
- Step 12: Establish Other System-Level Procedures
- Step 13: Prepare EMS Documentation (Manual)
- Step 14: Plan and Conduct Specific Employee Training

CHECK

Check: Checking, including monitoring and corrective action

As discussed earlier, your EMS should be built on the "Plan, Do, Check, Act" model to ensure that environmental matters are systematically identified, controlled, and monitored. Using this approach will help to ensure that performance of your EMS improves over time and that you meet your goals for implementing an EMS in the first place.

This stage continues the step-by-step action plan for developing and implementing the elements of an EMS. By this time, you should have sufficient EMS processes in place to begin to "check" your EMS. One approach is discussed below.

Conduct Internal EMS Audits

Once internal auditors have been selected and trained, you should design and initiate the internal auditing process. At this point, you should have sufficient EMS processes in place to conduct meaningful audits. Many organizations find that it is easier to start with smaller, more frequent audits than to audit the entire EMS at once. These early audits can serve as a learning tool. Audit records should be managed in accordance with the records management process. Once the audit results are known, use the corrective and preventive action process to address any identified problems.

Act: Reviewing, including progress reviews and acting to make needed changes to the EMS

This stage continues the step-by-step action plan for developing and implementing the elements of an EMS. At this point in the EMS Cycle, you may have identified problems with your EMS and should act to resolve these issues. One approach is discussed below.

Conduct Management Reviews

Use the results of your internal audits (along with other information on the EMS) to conduct management reviews. The management of your organization should consider the need for any changes to the EMS based on your review, and make assignments for any revisions needed. Such assignments should be consistent with the roles and responsibilities previously established. After acting on the results of the management review, tasks performed in the "Plan" stage should be revisited, thus continuing the "full circle" process.

ISO 14001 Structure and Basics

What are the changes?

- New high level structure

- EMS more prominent in the organization's strategic direction

- New requirement to understand the organization's context

- Greater commitment from leadership

- Implement proactive initiatives to protect the environment such as sustainable resource use & climate change mitigation.

- Focus on life-cycle thinking to ensure consideration of environmental aspects from development to end-of-life.

ISO 14001:2004 Structure

1. **Scope**

2. **Normative references**

3. **Terms and definitions**

4. **Environmental Management System**
   - Scope
   - Environmental Policy

5. **Planning**
   - Environmental Aspects
   - Legal and Other Requirements
   - Objectives and Targets

6. **Implementation and Operation**
   - Resources, Roles, Responsibility and Authority
   - Competence, Training and Awareness
   - Communication
   - Documentation
   - Operational Control
   - Emergency Preparedness and Response

7. **Checking**
   - Monitoring and Measurement
   - Evaluation of Compliance
   - Nonconformity, Corrective Action and Preventive Action
   - Control of Records
   - Internal Audit

8. **Management Review**

ISO 14001:2015 Structure

1. **Scope**

2. **Normative references**

3. **Terms and definitions**

4. **Context of the organization**
   - Understanding the organization and its context
   - Understanding needs and expectations of interested parties
   - Scope of the management system
   - Environmental management system

5. **Leadership**
   - Leadership & commitment
   - Environmental policy
   - Roles, responsibilities and authorities

6. **Planning**
   - Actions to address risks & opportunities
     - General
     - Environmental aspects
     - Compliance obligations
     - Planning action
   - Objectives and planning to achieve them
     - Environmental objectives
     - Planning to achieve objectives

7. **Support**
   - Resources
   - Competence
   - Awareness
   - Communication
     - General
     - Internal communication
     - External communication
   - Documented information
     - General
     - Creating and updating
     - Control of documented information

8. **Operation**
   - Operational planning and control
   - Emergency preparedness & response

9. **Performance evaluation**
   - Monitoring, measurement, analysis & evaluation
     - General
     - Evaluation of compliance
   - Internal audit
   - Management review

10. **Improvement**
    - General
    - Nonconformity and corrective action
    - Continual Improvement

Annex A – Informative Guidance

Annex B – Correspondence 2015 vs 2004

Bibliography

Alphabetical Index

> Key:
> Black – core MS requirement , comparable to 14001:2004 Red – New MS requirements Blue – ISO 14001, discipline- specific

2004 vs. 2015 changes

(Crosswalk available in electronic handouts)

ISO 14001:2015/GEMS Crosswalk

August 2015

ISO 2004 Standard	ISO 2015 Standard	ISO Changes
1. Scope	1. Scope	
2. Normative References	2. Normative References	
3. Terms and Definitions	3. Terms and Definitions	
4. Environmental Management System Requirements	4. Context of the Organization (Title heading)	New clauses requiring the organization determine the internal and external issues that can influence the scope of its EMS. Env. risks, opportunities, and stakeholder expectations

Mandates top management take the lead in integrating EMS into the strategies, processes and priorities |
| | 4.1 Understanding the Organization and its context | Organization is expected to gain a general understanding of the expressed needs and expectations of those internal and external interested parties. |
| | 4.2 Understanding the Needs and Expectations of Interested Parties | New commitment to compliance obligations (Compliance obligations is a new term replaces the term legal and other requirements)

Greater emphasis on determining risk profile |
| 4.1 General Requirements | 4.3 Determining the Scope of the Quality Management System

4.4 Environmental Management System | Assessment of the organizations external and internal issues relevant to its purpose and affect its ability to achieve intended outcomes |

2004 vs. 2015 changes

ISO 2004 Standard	ISO 2015 Standard	ISO Changes
	5. Leadership	**New Clause: Increased leadership commitment:** • **Taking accountability for the effectiveness of EMS** • **Ensuring policy and objectives compatible with strategic direction of organization** • **Integration of EMS into business practices** • **Ensuring adequate resources** • **Communicate importance of EMS**
4.2 Environmental Policy	5.2 Environmental Policy	
4.3 Planning	6. Planning **6.1 Actions to Address Risks and Opportunities** 6.1.1 General	6.1 and 4.1 cover the intent of preventative action.
4.3.1 Environmental Aspects	6.1.2 Significant environmental aspects **6.1.3 Determination of Compliance Obligations**	**New Terminology: Compliance Obligations new term that replaces Legal and Other Requirements.**
4.3.2 Legal and Other Requirements	6.1.4 Risks associated with **threats and opportunities**	**New Terminology: Threats and opportunities**
4.3.3 Objectives, Targets and Programme(s)	6.2 Environmental Objectives and planning to achieve them.(Title) 6.2.1 Environmental objectives 6.2.2 Planning actions to achieve environmental objectives	**Not only are significant environmental aspects and compliance should be considered when setting objectives but risk associated with threats and opportunities.**

2004 vs. 2015 changes

ISO 2004 Standard	ISO 2015 Standard	ISO Changes
4.4 Implementation and Operation (Title)	7. Support (Title)	
4.4.1 Resources, Roles, Responsibility and Authority	7.1 Resources 5.3 Organizational Roles, Responsibilities and Authorities 5.1 Leadership and Commitment	
4.4.2 Competence, Training and Awareness	7.2 Competence	**Competency of persons who can affect environmental performance it given a new sub-clause. (7.2)**
	7.3 Awareness	
4.4.3 Communication	7.4 Communication 7.4.1 General 7.4.2 Internal Communication 7.4.3 External Communication and Reporting	
4.4.4 Documentation	7.5 Documented Information (Title)	
	7.5.1 General	
4.4.5 Control of Documentation 4.5.4 Control of records	7.5.2 Creating and Updating 7.5.3 Control of Documented information	

2004 vs. 2015 changes

ISO 2004 Standard	ISO 2015 Standard	ISO Changes
4.4.6 Operational Control	8.1 Operational Planning and Control	**Life Cycle Perspective when identifying aspects. Address life cycle thinking and incorporate identification and evaluation of environmental aspects related to products and services more clearly. This does not require a Life cycle assessment (LCA) to be conducted.**
4.4.7 Emergency Preparedness and Response	8.2 Emergency Preparedness and Response	
4.5 Checking (Title)	9. Performance Evaluation (Title)	
4.5.1 Monitoring and Measurement	9.1 Monitoring, Measurement, Analysis, and Evaluation (Title)	
	9.1.1 General	
4.5.2 Evaluation of Compliance	9.1.2 Evaluation of Compliance	
4.5.3 Nonconformity, Corrective Action and Preventive Action	10.1 Nonconformity and Corrective Action	
4.5.4 Control of Records	7.5.3 control of Documented Information	
4.5.5 Internal Audit	9.2 Internal Audit	
4.6 Management Review	9.3 Management Review	
	10.0 Improvement (Title)	

Terms and Definitions New to ISO 14001:2015

▸ Compliance obligations (replaces legal and other requirements): Requirements that organization has to or chooses to comply with.

▸ Documented information (replaces documents/records)

▸ Leadership

▸ Risk

▸ Opportunity

▸ Environmental Conditions

▸ Life Cycle

▸ Outsource

Elements in 14001 (2015

- Chapter 1: Scope
- Chapter 2: References
- Chapter 3: Terms and Definitions
- Chapter 4: Context of the Organization
- Chapter 5: Leadership
- Chapter 6: Planning
- Chapter 7: Support
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- Chapter 10: Improvement

Context of the Organization

The organization must determine external and internal issues relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its EMS

External issues
- **Culture**
- **Political**
- **Legal**
- **Regulatory**
- **Financial**
- **Technological**
- **Economic**
- **Natural**

Internal issues
- **Activities**
- **Products and services**
- **Strategic direction**
- **Culture**
- **People**
- **Knowledge**
- **Processes**
- **Systems**

Context of the Organization

What are the Requirements

- Local Facility Strategic Plan

- Department of Veterans Affairs Strategic Sustainability Performance Plan

- VHA EMS Strategic Plan
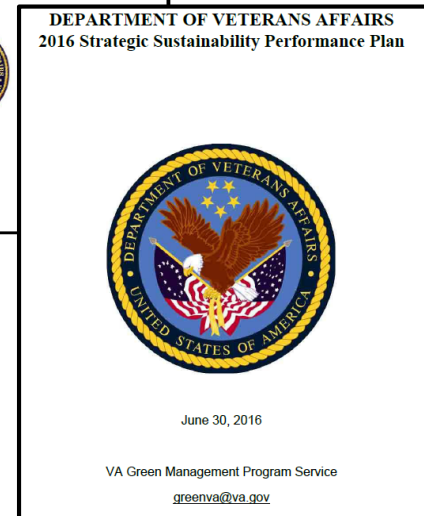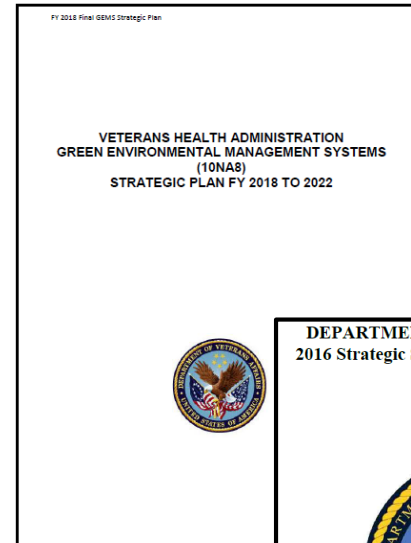
FY 2018 Final GEMS Strategic Plan

VETERANS HEALTH ADMINISTRATION
GREEN ENVIRONMENTAL MANAGEMENT SYSTEMS
(10NA8)
STRATEGIC PLAN FY 2018 TO 2022

DEPARTMENT OF VETERANS AFFAIRS
2016 Strategic Sustainability Performance Plan

June 30, 2016

VA Green Management Program Service
greenva@va.gov

Context of the Organization

Understanding the needs and expectations of interested parties

The organization must determine:

- *Interested parties relevant to the EMS*

- *The relevant needs and expectations of those interested parties*

- *Which of these needs and expectations become compliance obligations*

Interested parties may include:
    Veterans
    Veterans Groups
    Member of Congress
    Employees
    Community/Neighbors
    Suppliers
    Regulators

Leadership

Top management shall demonstrate leadership and commitment with respect to the EMS by:

- Appointing an EMS Program Manager

- Taking accountability for EMS effectiveness

- Ensuring the environmental policy aligns with facility strategic plan

- Ensuring the environmental policy is communicated

- Ensuring EMS resources are available

- Establishing a multi-disciplinary Committee

Planning

Facility will select significant environmental aspects, meet its compliance obligations, and define objectives and target to guide continual improvement.

- Environmental Aspects that includes a risk assessment

- Significant aspects determined and used to establish objective, targets and EMPs

- Compliance obligations identified

- Objective and targets for significant aspects – measurable and improving control

- Priority given to those impacts that have greatest impact on compliance

- Monitoring and reporting of objectives and targets through GEMS Committee

- Annual EMS Management Review

Support

Facility will commit resources to the EMS Program:

- Senior management must provide resources to implement and operate an effective EMS Program

- Competencies

- EMS Awareness Training

- New Employee Orientation Training

- Training Plans

- TMS Training Courses

- Communication (Internal and External)

- Documented information

Operation

Explicit requirements for establishing criteria and implementing process control.

- Establish operational controls procedures for ensuring compliance obligations are met

- Places greater emphasis on "life cycle perspective."

- Does not require a detailed life cycle assessment – just a simple consideration of the life cycle stages which can be controlled or influenced.

- Looks at how organizations control changes and outsource specific processes.

- Emergency Planning and Response

How can you develop explicit requirements for establishing criteria and implementing process control?

- ➢ Use Existing Facility Policy Documents and SOP's – don't reinvent the wheel!

  - ➢ Skim through all the facility's policies and procedures and start a spreadsheet to list any that include an "environmental activity"
    - ➢ Do the same with all the SOPs for every department
    - ➢ Find any that you could possibly insert even the smallest EMS requirement (you don't need to create a whole new document…)

  - ➢ "Trace" SOPs referenced in Policies that are of interest to the EMS and put those on your list

  - ➢ Review all procedures of interest for potential inclusion of a compliance requirement and request a change from that department – then offer to train their staff on that change

Create a Master Matrix that indexes your EMS Documents

➢ Create a spreadsheet

- ➢ Crosswalk all policies with supporting SOPs, Legal Requirement, Responsible parties, Record locations, and training

- ➢ Pull out actions and responsibilities by duty title into one sheet and that can serve as your roles and responsibilities matrix

➢ Supplement SOPs with Job Instructions, Posters, Training slides

- ➢ Develop a timeline and schedule for reviews – this may be a 2-3 year cycle

- ➢ Work closely with shop supervisors to insert your requirement into anything they already have

- ➢ Offer to help train and participate in "shop talks"

Example Matrix and Focus Checklist included in electronic files can be used to develop your master index of your EMS

➤ Example tracking tools
  ➤ CR/AM Model

COMPLIANCE REQUIREMENTS / ASSESSMENT MATRIX (CR / AM)					
Site	Medical Center USA		Date Created	1-Jun-14	
Address			Date Updated	31-Jul-14	
Point of Contact			Revision Number	3	
Phone					
Email Address					
EPA ID					
Significant Aspects	Objectives/Targets	Monitoring		Permit Condition	Legal Requirement	Roles & Responsibilit
		Task	Frequency/Due Date			
Air Emissions Management						
	Manage Ozone Depleting Substance Management Program					
		Review HVAC Shop's ODS licensing & service records	Annually	NA	40 CFR Part 82.166(I)	Maintenance technicians
		Perform inventory of all equipment containing greater than 50 lbs of refrigerant	As needed, review annually to ensure inventory is up to date	NA	40 CFR Part 82.166(k)	Maintenance technicians
	Maintain compliance with National Emission Standards for Hazardous Air Pollutants					
		Asbestos Inspections prior to Demolitions	As needed, prior to State Notifications.	N/A	40 CFR Part 61.145(a)	GEMS Coordin
		State Notifications (Asbestos) prior to demolitions/renovations	10 days prior to any demoliton or renovation	N/A	40 CFR Part 61.145(b)(3)(iii)	GEMS Coordin
Water Management						
	Safe Drinking Water Act Compliance					Engineering

Performance Evaluation

Facilities will develop and maintain procedures that describe how it will monitor, measure, analyze, and evaluate its environmental performance:

- System to monitor, measure and evaluate data for continual improvement

- Continual improvement opportunities are identified from the following:

    - ✓ External benchmarking

    - ✓ Change to compliance obligations

    - ✓ Audit results

    - ✓ Monitoring of operations

    - ✓ Views of interested parties

Improvement

Facilities will determine opportunities for improvement and implement necessary actions to achieve the intended outcomes of its EMS

- Procedures to address non-conformities and take corrective and preventive action

- Facilities will continually improve the EMS Program

EMS Auditing
Some Observations

- ISO 14001 Lead Auditor Training
  - Focuses on the "set up" of the EMS and Procedures on how to run your EMS
  - Necessary to Certify your EMS
- Conformance
  - Conformance – does your EMS meet the ISO standard?
  - Do your procedures keep you in compliance?
  - Are people following your procedures?
- Compliance
  - Are you in compliance with the regulatory requirements?
  - Compliance audits tend to result in "tickets"
  - Tickets get closed and magically you are in compliance??
- What if you are not going to get certified???
  - ISO 14001 can serve as a framework
  - Staff can focus on developing operational procedures vs. ISO procedures
  - Goal is to have procedures that keep you in compliance with regulations vs. a standard

Shift to EMS Auditing Based on Compliance Auditing Data

Problem:

- Past focus of VHA EMS Audits
    - Review of the procedures that set up the structure of the GEMS
        - How to do your Aspects and Impacts, how you set your goals/objectives, etc.
        - Review of if the EMS procedures were done, some examples:
            - Aspects and Impact lists
            - Master Policy current
            - Annual review, Goals objectives
    - Tended to end up being a review of things the GEMS manager would do vs. do the various shops/departments have adequate procedures and are they following them

- EMS audits sometimes ended up being a Compliance Audits?
    - Audits included compliance findings, but yet no program findings on procedures that need improvement?
    - Annual compliance audits may result in too many findings from multiple audits and cause the treadmill affect where sites spend more time fixing tickets and can't get programs set up or implemented?

# Using Compliance Data to Establish the Scope of your Audit

- In depth review of all Environmental Procedures takes a lot of time
  - Typical audit has to be done in 2 days
  - Auditors wearing multiple hats and travel restrictions mean limited time in field
- Lessen the emphasis or eliminate review of the actual structure and running of the EMS
- More focus on review of actual site specific programs for the regulated aspects (medias)
  - Not a compliance audit but an audit of the local procedures and processes that keep regulated activities in compliance
  - An audit of the EMS's Environmental Policies, Procedures, and Processes
    - Have the sites created customized media based procedures either stand alone or embedded in other similar VAMC policies (Engineering, EMS, Pharmacy, etc.)?
    - Are the written programs something that laymen can follow, would they keep the site in compliance, do they say who does what, are they followed?
    - Does the GEMS routinely evaluate the procedures and improve them as necessary?

Refocusing the EMS Audit based on compliance data

- Compliance data includes common root cause – maybe audit the EMS component where we have failure based on the root cause?

- #1 cause – Inadequate procedures or failure to implement procedures

- What if you skip the ISO conformance to the standard and just looked at the hands on procedures that should be in place to keep the "aspects" in compliance??
  - Review the procedures to see if they "conform" to regulatory requirements
  - Then review if the staff is conforming to the processes

EMS Auditing Based on Compliance Auditing Data

Maybe Audit a Media Based Program Area Based on Past Compliance Findings?

Program Areas with Most Findings/Yr (Pareto %)
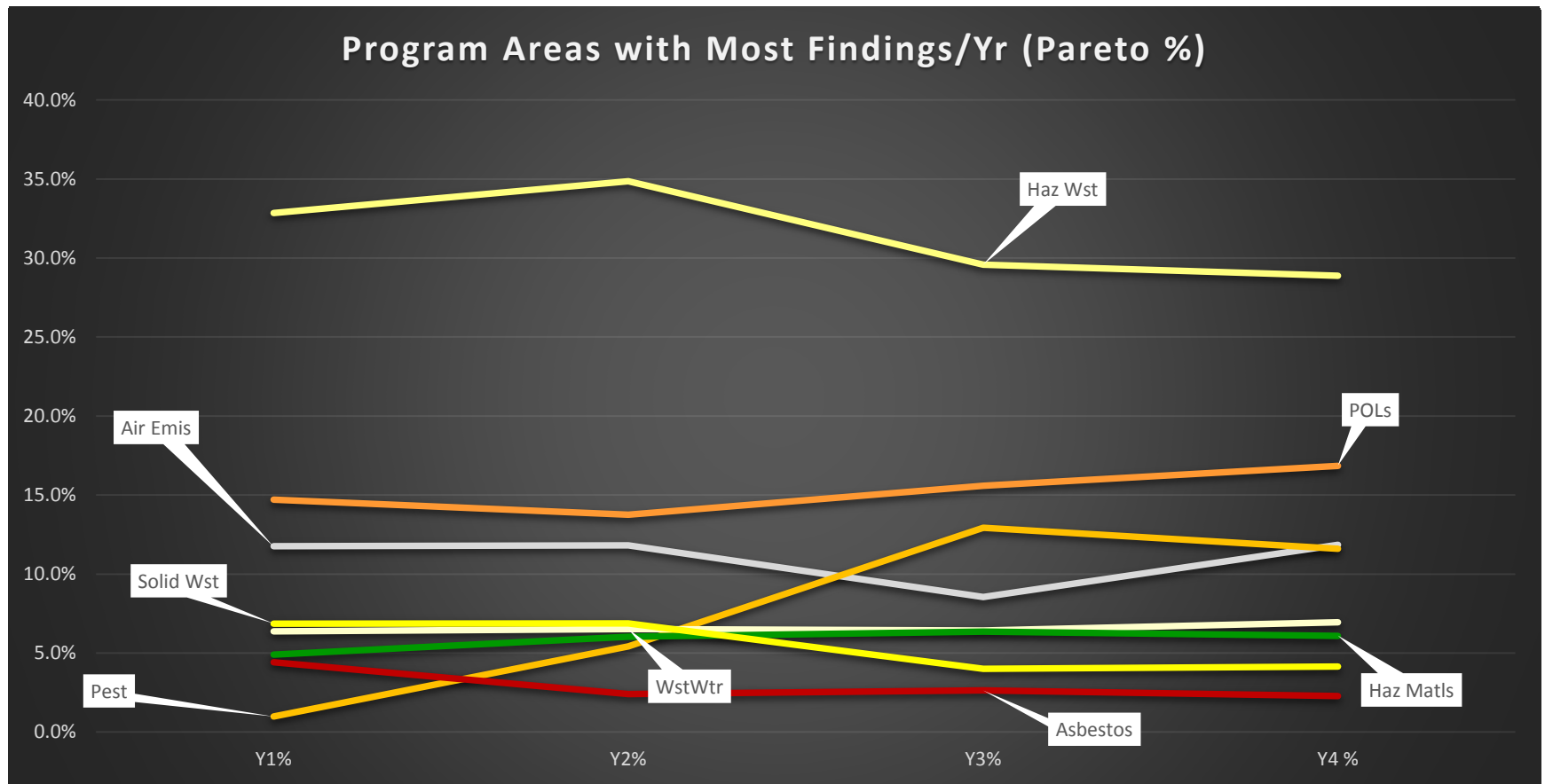
Migrate the EMS Review to a Few Media Based Programs to Limit Scope by using Focus Areas

Looked at 2 Options to Determine Focus Areas Based on Past Data

1. Data Specific to the Site using a Hierarchy approach
   - NOV? If yes, customize checklist to thoroughly review that regulatory area (UST Example)
   - If No, use past 3rd party finding data to look at trends (SPCC Example)
   - Add National Focus Area (Pharma Waste)
2. New Regulations Focused using National Focus Area
   - Applicable New Regulations to Our Operations
     - Pharma Waste, Refrigerant Recordkeeping
   - New Regulations may require changes in local Hospital procedures to comply
     - Pharma Waste Program
   - Based on repetitive problem areas from 3rd party audits
     - HW/Pharma Waste, Refrigerant Recordkeeping

Both Options Include Review Based on Addressing Top Root Causes from Last Compliance Audit Data
   - Are Completed Corrective Actions working?

VHA FY 2020 Focus Areas

- Scope of FY 20 VHA Audits Will Use National Focus Areas (Option 2)
  - With limited time this can allow for a thorough quality review rather than trying to accomplish an across the board audit of all program areas
  - Compliance Audits are already done by the 3rd parties every 3 years
  - VISNs can provide better consultative assistance and help sites formulate better action plans to really address lack of hospital procedures and implementation of processes

- Status Check of latest 3rd Party Audit Findings
  - Desk Audit with GEMS manager to review how findings were closed or status of open ones
    - Document the local process/procedure associated with each finding
    - Is site monitoring activity for continual compliance
  - Brief Physical Inspection of the last 3rd party Finding Activities/Operations to observe if corrective actions were successful
  - Assist in corrective action plan development via recommendations and consultation with GEMS manager during visit
  - Assist in training responsible staff as requested

VHA FY 2020 Focus Areas

Focus Medias

- Refrigerant Management Recordkeeping Procedures

- Site has or is in process of updating all applicable Policies and SOPS to address new Pharmaceutical Waste regulations
  - Hospital wide policy is in place to make all staff aware of sewering prohibition
  - Services with Pharmaceutical Waste have drafted written procedures for properly handling the waste under the new rules
  - VISN should provide consultation on how to best update policies
  - Facilities should be working with HW haulers to develop a practical and economical process for sorting and packaging
  - Assist in reviewing and recalculating Generator status and Facility has properly calculated their generator status for current operations and has plans for how this will be adjusted after their state rules become final
  - Provide consultation and VISN wide direction on standardizing within your states and ensure vendor contracts have a practical and economical process for sorting and packaging

Developing the Checklist and Criteria Statements (Example Checklist included in Electronic Handouts)

- Steps
  - Utilize the Focus Checklist to conduct a detailed review of the 2 Regulatory Requirements
  - Insert any State Specific Recordkeeping Requirements or Permit conditions
  - Obtain the latest All Findings Spreadsheet and Import Last 3rd Party findings into the Focus Checklist
  - Note any discrepancies or needs for improvement in CPTrack as findings utilizing the provided TEAM criteria statement
    - Carry overs (use for open items)
    - Repeats (only be for same item and location)
  - Attach Focus Area Checklist to the CPTrack Audit using the audit level attachment function

Auditing for Conformance

- Review written policies and procedures for the Focus Areas and last 3rd party findings
  - Document the reference to the specific Policy/Procedures
  - Does the policy/procedure adequately assign roles/responsibilities and provide procedures to ensure compliance?
  - Do responsible staff understand procedures and are following them?
  - Is an oversight mechanism in place to routinely inspect and ensure tasks assigned to maintain compliance are completed.

- Utilize a "Tracer" method to audit procedures

- Ask the 5 Why's to determine root cause

- Do desk audit in advance to maximize time in field for interviews and physical observations.

Conclusion

- The ISO framework provides the tool to establish local programs and procedures, but if certification is not the goal extra work load to maintain "EMS Documents" detracts from work on improving hand's on procedures

- Field testing of audit conclusions
  - Hierarchy Method would not provide as much standardization
  - EMS Audits conducted in conjunction with 3rd party audits are cumbersome in the review of last compliance audit (Changes are going to be made for those sites to allow use of new findings in checklist)
  - In depth review of just a few focus topics does take a lot of time so auditors need to maximize the use of prior desk auditing

Questions???

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