

# Guess Who's Coming to Inspect?

Wanda Koetz, RN, HP (ASCP)

American Red Cross

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# Content

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- Inspecting agencies
- Preparing staff
- Training
- Internal audits
- Conducting inspections
- Checklist
- Summary
- Questions



# Inspecting Agencies

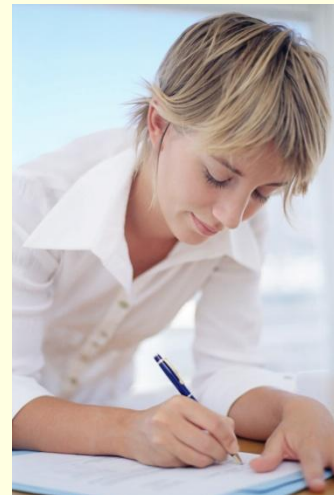
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- FDA
- AABB
- JCAHO
- OSHA
- State agencies
  
- Internal auditors

# Preparing Staff

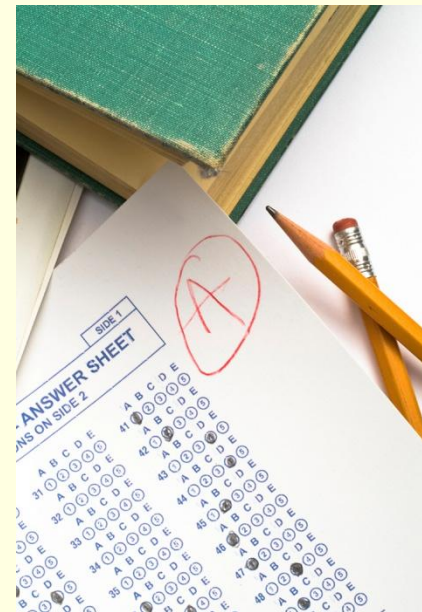
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- Hiring the right people
  - Attention to detail
  - Thorough
  - Able (and willing!) to follow direction
  - Ability to think



# Preparing Staff

- Adequate and appropriate training
  - Regulations
  - Procedures
  - On-the-job training
  - Assessments
  
- Training Records



# Preparing Staff

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- Training must:
  - Adequately prepare staff to perform the tasks correctly
  - Ensure staff are not performing tasks they have not been trained to perform

# Preparing Staff

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- Role-playing



- Answer only the question asked – do not offer additional information

# Preparing Staff

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- It is acceptable
  - To say “I don’t know but I’ll find out for you.”
  - To look something up in the procedures
  - To ask the supervisor for help

# Internal Audits

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- Purpose:
  - Verify that processes and procedures meet at least minimum requirements
  - Verify that staff perform procedures correctly
  - Identify best practices that may be helpful in other departments/facilities

# Internal Audits

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- Help to prepare staff for outside audits such as FDA and AABB
- Provide opportunity to identify areas for process improvement

Note: Internal audits usually focused to a specific department or issue

# Internal Audits

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- General audits should be periodic and routine
- Focused audit usually done as needed for a specific situation or need
- Conducted by non-biased staff, usually QA

# Internal Audits

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- Use of a checklist helps to ensure all areas are assessed and all affected staff are measured against the same criteria

[http://www.fda.gov/BiologicsBloodVaccines/  
BloodBloodProducts/RegulationoftheBloodSupply/  
ReviewChecklist/default.htm](http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/RegulationoftheBloodSupply/ReviewChecklist/default.htm)

Version July 2006

# Internal Audits

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- Reported to senior management
- Written response and corrective action are required - ensures that identified deficiencies have been addressed with corrective action that has been effective



# Conducting Inspections

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- Internal procedures for conducting inspections
  - Outline responsibilities
  - Outline documentation requirements
- Facility lead
  - Represent organization
  - Daily notes of what transpired
  - Log of materials provided to inspectors

# Conducting Inspections

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- Line staff
  - Answer questions
  - Perform tasks according to procedures



Thank you!