



EAGLE Registrations Inc.
I N T E G R I T Y • S E R V I C E • V A L U E

EAGLE INSIGHT
“EXPERIENCE SPEAKS OF LESSONS LEARNED”

Quality People With Quality Advice!

ASQ Section 1201 - Chicago
October 8, 2008

INTRODUCTIONS



EAGLE Registrations Inc.
INTEGRITY • SERVICE • VALUE

- Nancy Berger, Sales Manager
EAGLE Registrations Inc.
- Bill Jefferies, Lead Auditor



FROM AUDITORS INSIGHT

Quality People With Quality Advice!



Issue: Understanding if Your Quality Management System is Ready to be Assessed by a Registrar

Corrective Action Strategies:

- Strengthen Management's understanding of ISO Standard and Management Review
 - Analysis to see required documents in place
 - Processes are defined and in place
 - Measurables are collected
 - Internal audits effective
 - Corrective and Preventive actions taking place
 - Effectiveness being tracked



Issue: Overcoming Perception That ISO is a Function of the Quality Control Department

Corrective Action Strategies:

- Top Management spear-heading involvement of all employees
- Top Management needs to communicate the Company's Quality Policy and Goals to all employees and clarify their understanding



Issue: Lack Of Management Commitment to ISO System

Corrective Action Strategies:

- Management attend ISO training classes (can be internal or external)
- Clearly define Management team
- Be committed to Management Review process
- Management and ISO Management representative working together towards the same goal



Issue: Lack of Having Auditable Documented System

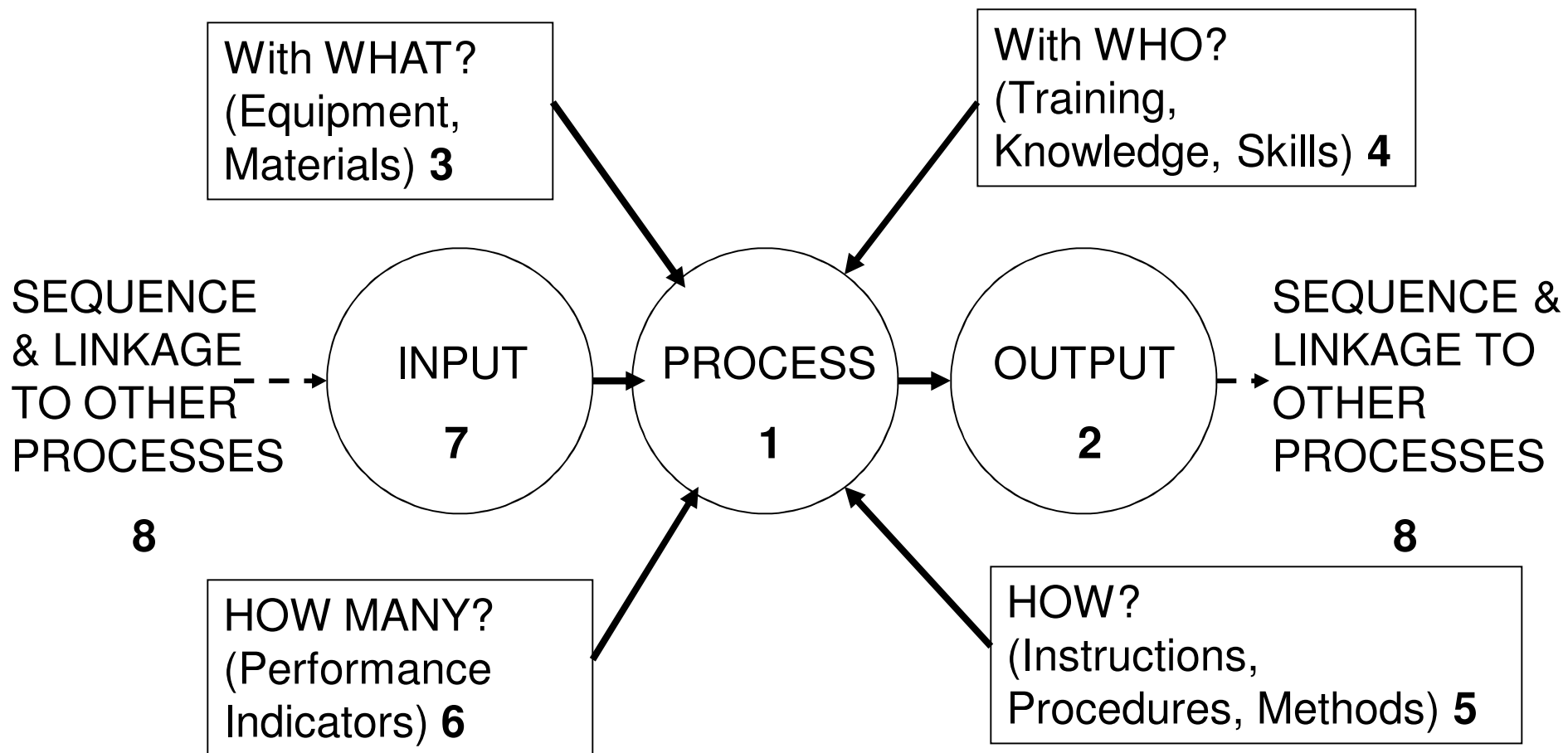
Corrective Action Strategies:

- Organization chart – responsibilities
- Process maps and charts
- Policies and Procedures
- Create and continually update documents



Process Auditing

- Turtle Diagram – Key Questions About a Process





Issue: Excessive, Cumbersome Documentation

Corrective Action Strategies:

- Not everything needs a written procedure unless the absence of written procedure would impact system performance
- Say what you do; Do what you say!
- Create simple, but precise documents and let people try them - if they are not understood then add more
- Take credit for what you already have in place - You do not have to reinvent yourself to become ISO certified



Issue: Consultant's System in Place Instead of Client's System

Corrective Action Strategies:

- Create *your* ISO system around *your* business practices
- Make sure your consultant understands your business and works to enhance/improve your system
- Do not make it cumbersome (i.e. procedures/records/systems that do not add value)



Issue: Lack of Knowledge of Customer Specific Requirements CSR

Corrective Action Strategies:

- Contract review for CSR
- Document them under your operational guidelines (in-house product specification)
- Maintain current customer manual – assign ownership of this process
- Include CSR requirements on production paperwork



Issue: Determining What Measurables are Important to Processes and Managing Them

Corrective Action Strategies:

- Define what is already being measured
- Define how currently defined measures link to current processes
- Define the measurables for the balance of the key processes
- Define what measurables are required by the standard (TS)
- Document, train, track and look for improvements



Issue: Auditing by Each Element of the Standard Rather Than by Process Approach

Corrective Action Strategies:

- Process diagrams
- Train internal auditor on process approach
- Create key process auditing form and reference the ISO applicable elements of the standard
- Understand the hand-off points between your processes, who is responsible and performance measurables



Issue: Improper Identification of Root Cause, Ineffective Corrective Action Plan and Ineffective Implementation

Corrective Action Strategies:

- Appropriate personnel resource allocation
- Training on root cause analysis
- Corrective Action methodology (i.e. use of 5Why, 8D)
- Internal auditing for effectiveness of corrective action plan
- Top Management reviewing corrective action effectiveness at Management Review



Issue: Past Due: Calibrations; Audits, Management Reviews

Corrective Action Strategies:

- Utilize computer to track and stay on top of schedule (software packages available)
- Management review should be the tool for weaknesses in your system



Issue: Preventative Action Records

Corrective Action Strategies:

- Take credit for your “Plans/Suggestions” (i.e. FEMAS, POKA YOKE)
- Companywide understanding on how to document your preventive actions



FROM CLIENTS INSIGHT

Quality People With Quality Advice!



Issue: How do I Know I am Interpreting the Standard the Way it was Meant to be Interpreted?

Corrective Action Strategies:

- Utilize web resources from Accreditation Bodies (i.e. IAOB/ANAB –Frequently Asked Questions and Lessons Learned)
- Utilize Consultant
- Look for User Group WebEx – sharing knowledge
- ASQ networking



Issue: Making Sure I Am Meeting ISO Requirements for Customer Satisfaction

Corrective Action Strategies:

- Survey – “Would you recommend ME to a business associate?”
- Cover all aspects of your business
- Follow-up 1 on 1 with any issue
- Have *a person* in charge of reviewing this data and assigning responsibilities



Issue: Perceived Audit Value Verses Audit Cost

Corrective Action Strategies:

- Look at your internal and external audits to find areas for improvement and trends
- ISO training adds value through better understanding of ISO requirements and their relationship to your processes
- Potential resource sharing with other ISO companies (i.e. combined training course)
- Research State/Federal Government for any grant money (usually for training)
- Understand how Nonconformance's (NCRs) and Opportunities for Improvement will strengthen your company's processes



Issue: Communication Misunderstandings Between Client and Registrar/Auditor

Corrective Action Strategies:

- Make sure you understand the Registrar audit process – ask for documentation
- Clarify with auditor their exact audit schedule – what/when
- Clarify questions –during audit
- Get a copy of the auditors report
- Call your registrar if you need their help resolving any issues (before, during and after audit)



Issue: How Do I Strengthen my Internal Auditing Team's Performance?

Corrective Action Strategies:

- Shadow Registrar's audit team
- Consider External Lead Auditor's Training Course
- Consider Communication Skills training
 - Ask Open Ended Questions
 - Ask Questions in a non-threatening approach
- Management support on the amount of time needed to complete an affective audit.



Issue: Understanding Your Registrar's Corrective Action Timeline

Corrective Action Strategies:

For example EAGLE's requirements:

- 30 Days From Close of Audit to Accept Corrective Action
- 60 Days from close of audit to send objective evidence corrective action plan implemented
- 90 Days from close of audit to close out the audit
- Following audit, Auditor will receive objective evidence of effectiveness of corrective action plan implemented



EAGLE Registrations Inc.
INTEGRITY • SERVICE • VALUE

For Additional Information, contact

EAGLE Registrations at:

(800) 795-3641

or

info@eagleregistrations.com

THANK YOU!