

mc²



Aras Innovator for Your Quality System

Don Stephen – Crucis Technology

Maureen McAllister – McAllister Consulting



Aras Community Event
May 2010

Primary Drivers for PLM?

- ❖ Requirement from Customer
 - ❖ Need to 'Control' my drawings
 - ❖ Need to 'Control' EBOMs
 - ❖ Improve Time to Market
 - ❖ Improve Product Support
 - ❖ Improve Project Management
 - ❖ Came Down from 'On High'
-

Reason NOT heard justifying PLM

I can create an easy to use,
invisible quality system!!!!

Navigating the Regulatory System Soup

ISO 9001

ISO / TS 16949

ISO 14001

AS9100 and FAA

21 CFR 820

TL 9000

and more...

What is ISO 9001?

- ❖ International standard –

- ❖ process focused and not product specific

- ❖ a set of requirements related to product and service provision to which an organization “registers”

- ❖ if done properly, creates a mind set that drives business performance:

- ❖ Speed to market

- ❖ On-time delivery

- ❖ Integration and communications

- ❖ Internal efficiencies

Quality System = Business System

ISO views your business as a customer would:

- ❖ Meeting customer requirements
 - ❖ Consistent, robust processes in all aspects of the operation
 - ❖ Performance focused
 - ❖ Driven by continual improvement
-

Quality is the Central Unifying Theme

Key performance metrics:

- ❖ Internal processes – performance vs. goals
 - ❖ Customer satisfaction in the broadest sense
 - ❖ Easy to do business with = reliable & consistent
 - ❖ Focused on quality, delivery, value
 - ❖ Data-driven decision making
-

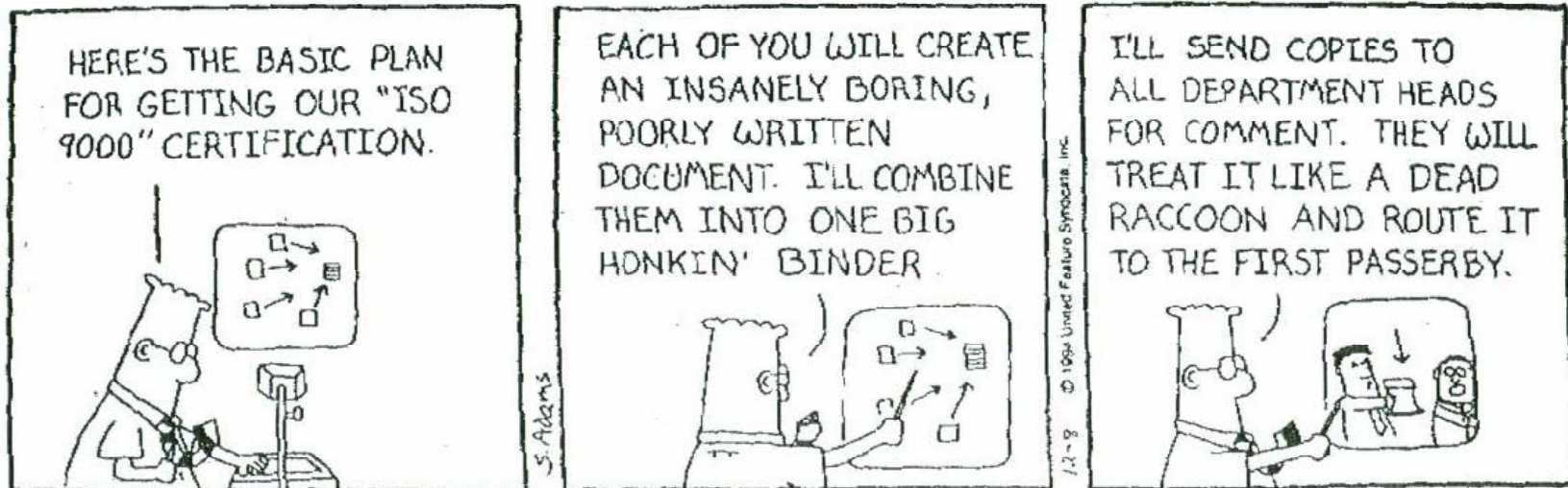
Quality = Linkages and Interfaces

- ❖ Where does the ball get dropped?
Manage those interfaces intensely with data, not personalities.
 - ❖ ISO requires that an organization define its key business processes AND the interfaces amongst these
-

Aras Innovator + ERP = facilitating ISO

- ❖ Innovator and ERP = managing data and transactions so functions/activities “talk to” each other.
 - ❖ ISO drives the same interface management, with customer satisfaction as the ultimate measure of success
-

Getting Started



Getting Started

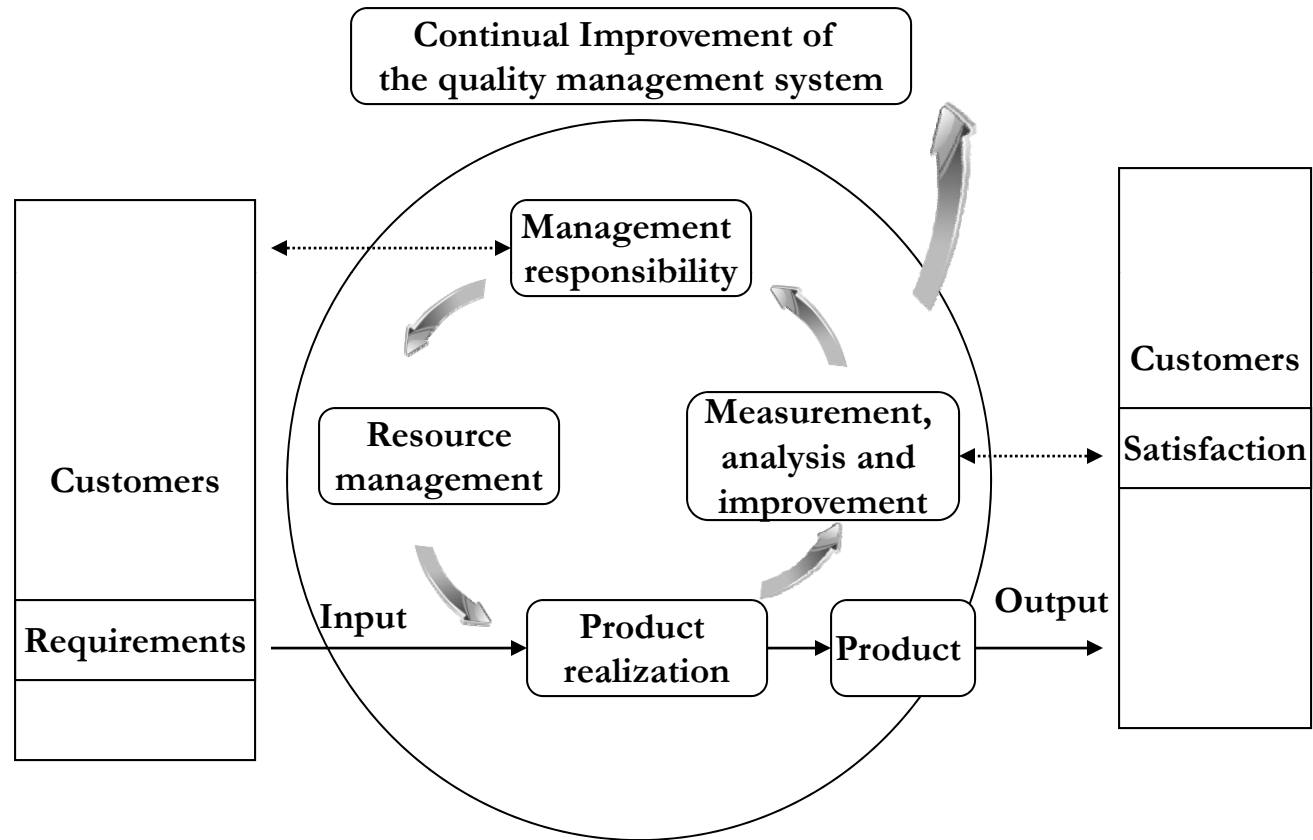
❖ Keep 5S 'Top of mind'. **One Stop Shopping**

(Sorting, Straightening, Shining, Standardizing, Sustaining)

- ❖ Perform a Gap Analysis 'Aras Innovator Solutions vs. Quality Standard'.
 - ❖ Analyze gaps
 - ❖ Group (build logical packages).
 - ❖ Review Aras Projects pages for other packages.
 - ❖ Morph (Leverage Aras Innovator capabilities and current Solutions items to fill gaps).
 - ❖ Support (lists, reports, itemtypes,...).
 - ❖ Prioritize your packages to Enterprise needs
-

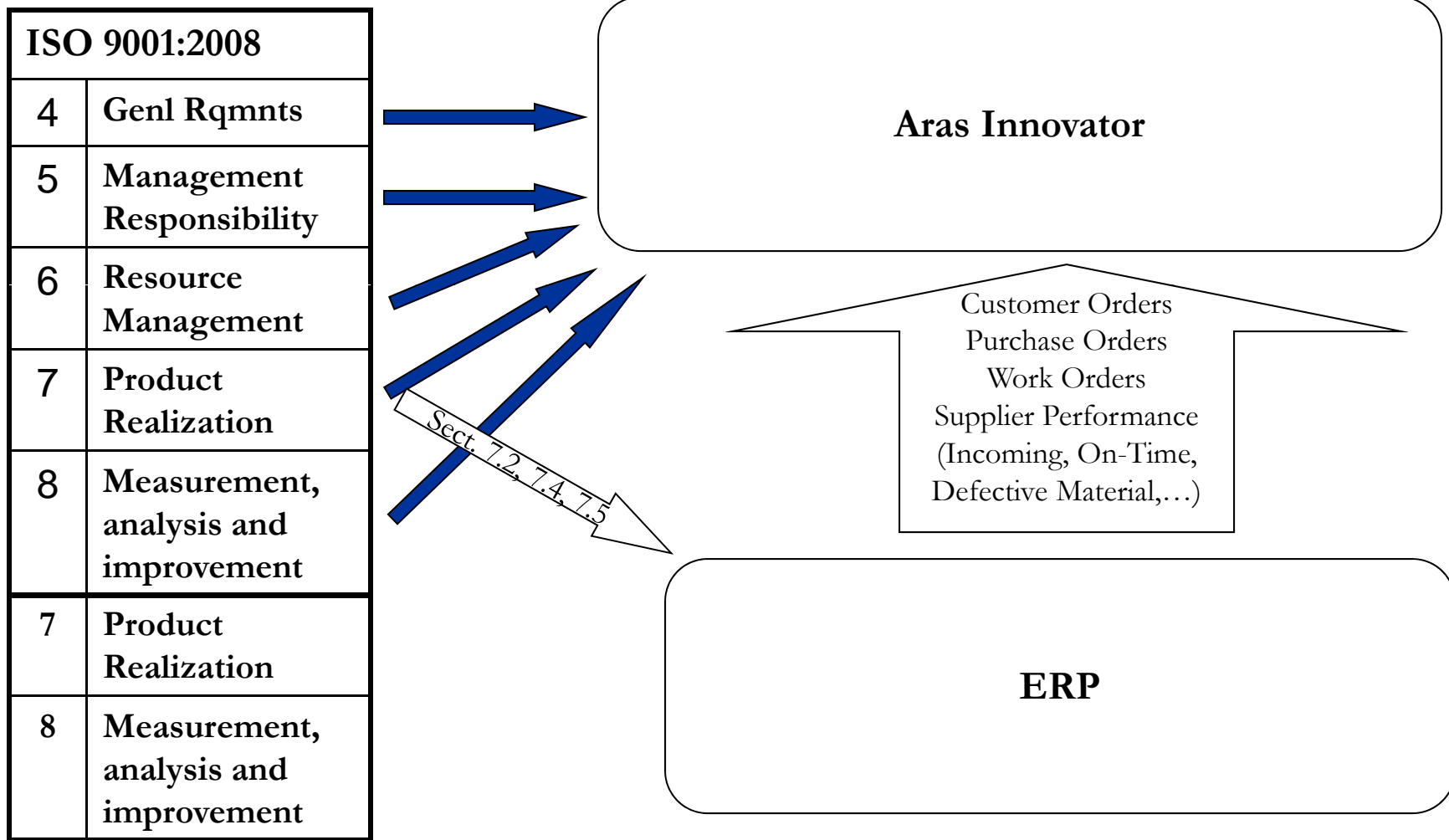
How well does Aras Innovator Fit as a Quality System?

ISO 9001:2008	
1	Scope
2	Normative Ref.
3	Terms & Def
4	Genl Rqmnts
5	Management Responsibility
6	Resource Management
7	Product Realization
8	Measurement, analysis and improvement

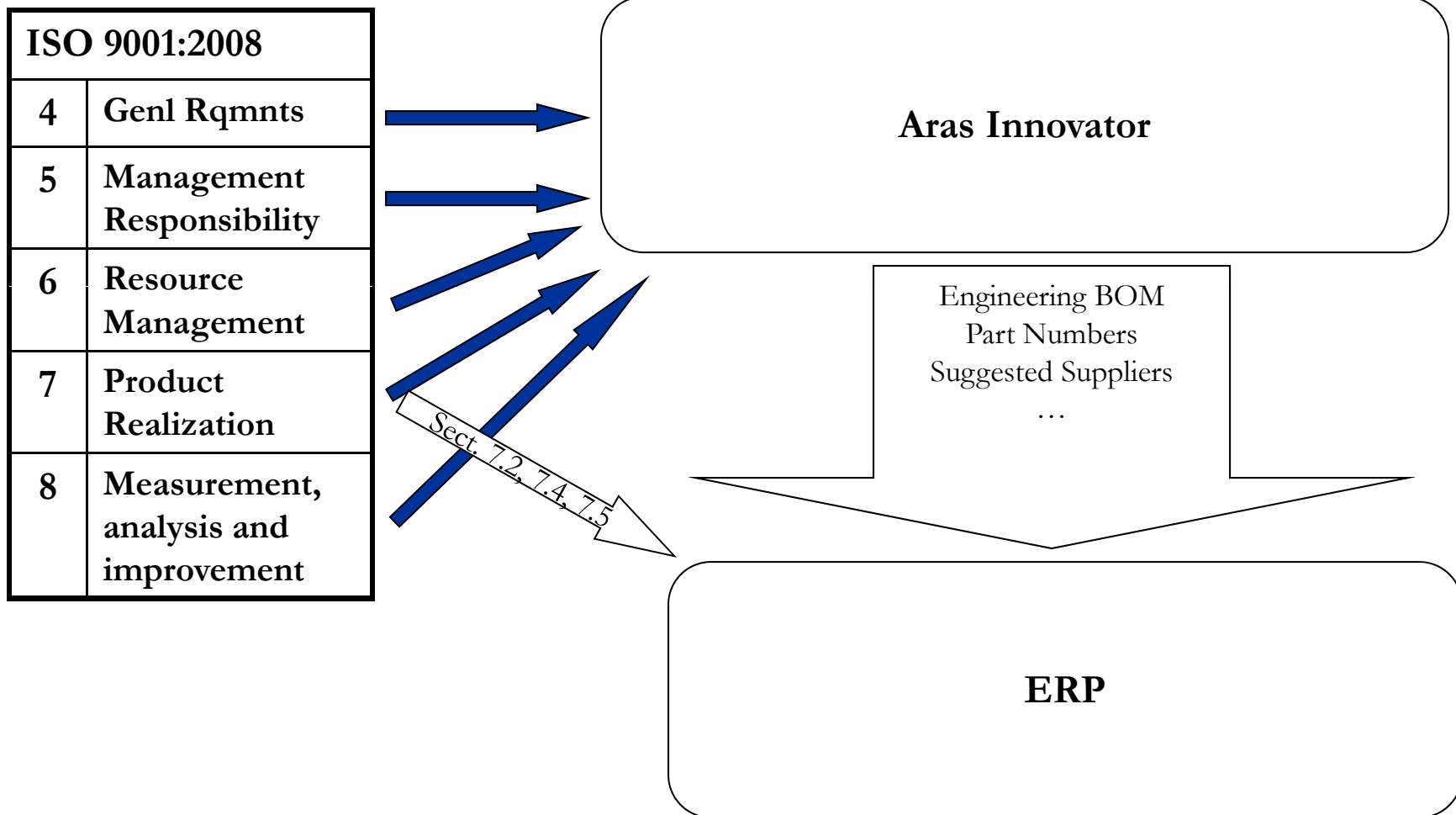


From ISO 9001:2008

ISO => PLM or ERP



ISO => PLM or ERP



Example of Compliance Matrix

ISO 9001:2008 Compliance Summary				
Section	Section Title	Notes	How addressed by Innovator and Solutions db	Innovator GAP
7.4	Purchasing			
7.4.1	Purchasing Process	<ul style="list-style-type: none"> a) purchased product conforms to purchase requirements b) eval and select suppliers based on their ability to meet organizations requirements c) criteria for selection, evaluation and re-evaluation shall be maintained. 	Supplier Qualification and evaluation data are often found in the "vendor master" or similar facility within many ERP systems. In addition, actual supplier performance data (e.g., performance to requested delivery dates/quantities; items rejected/returned to vendor, etc. are also part of most ERP systems. These data may be extracted and tracked as input to process performance metrics (4.1) and to Mgt. Review (5.6).	Will need to be enhanced for selection and performance monitoring
7.4.2	Purchasing Information	<ul style="list-style-type: none"> describe the product: a) reqmt for approval of product, procedures, processes and equipment. b) reqmt for qualification of personnel c) GMS reqmts 	Part Item Type. See purchasing controls and data extractable from the ERP system. The linkage between the ERP system and the Product revision level controls within Innovator can be used to help ensure that supplier receive correct and updated revision level input on POs for made-to-spec items.	May need additional properties added based upon classification of parts if customer wants the additional granularity.
7.4.3	Verification of Purchased Product	establish inspection or other to ensure product meets reqmts	Incoming inspection data (as determined in reference to controlled work instructions that define inspection criteria, frequencies, lot sizes, etc. maintained in Innovator) are available through most ERP systems. Likewise, data related to supplier reject/returns are typically maintained within an ERP system. These data may be extracted and analyzed within Innovator.	This would likely be a part of ERP. Would want this to be an interface point so material issues can push info directly to customer performance.
7.5	Production and Service Provision			
7.5.1	Control of Production and Service Provision	<ul style="list-style-type: none"> Carry out production and service provision under controlled conditions that include: a) info describing characteristics of product b) availability of work instructions c) use of suitable equipment d) availability and use of monitoring and measuring equipment. e) implementation of monitoring and measuring equipment. f) implementation of product release, delivery and post-delivery activities. 	Document Management & Change Management. Likely applications for Innovator: work instructions (pictorial, narrative, etc.) for individual products - their manufacture, test, packaging, etc; work instructions for equipment and tooling maintenance (or data extracted from standalone pm or other system); electronic availability at work cell.	If Change Management process is too heavy would need to use light weight version
7.5.2	Validation of Processes for Production and Service Provision	<ul style="list-style-type: none"> Validate processes for production and service provision (deficiencies only appear after delivery/in service) a) defined crit for rev and approval of processes b) approval of equip and qual of personnel c) use of specific methods and procedures. d) reqmts for records e) revalidation 	See 7.5.1 comments	<ul style="list-style-type: none"> a. Criteria creation would be a management effort. b. An ItemType to track equipment and approval process, calibration records and requirements.

Grouping Example

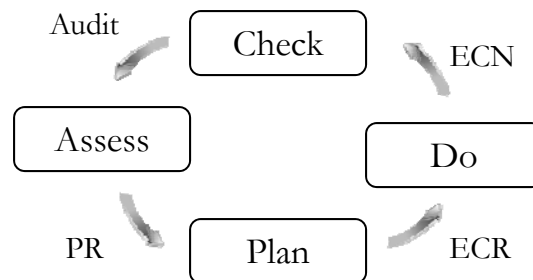
- ❖ ERP linkage
- ❖ Competency Matrix
- ❖ Audit Item
- ❖ Inspection Item
- ❖ Training History
- ❖ Non Conforming Material
- ❖ Corrective Action
- ❖ Preventive Action



- ❖ ERP linkage
- ❖ Resource Management
 - ❖ Competency Matrix
 - ❖ Training History
- ❖ Audit/Inspection Item
 - ❖ Non Conforming Material
- ❖ Corrective Action Preventive Action

Morphing

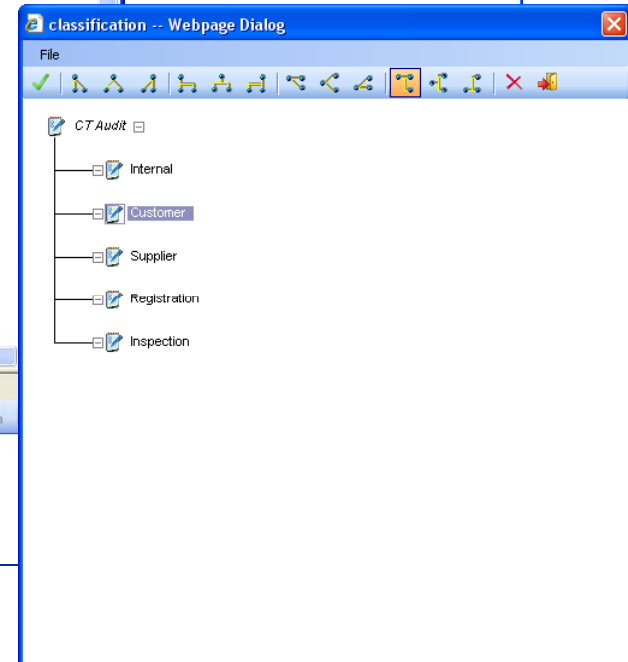
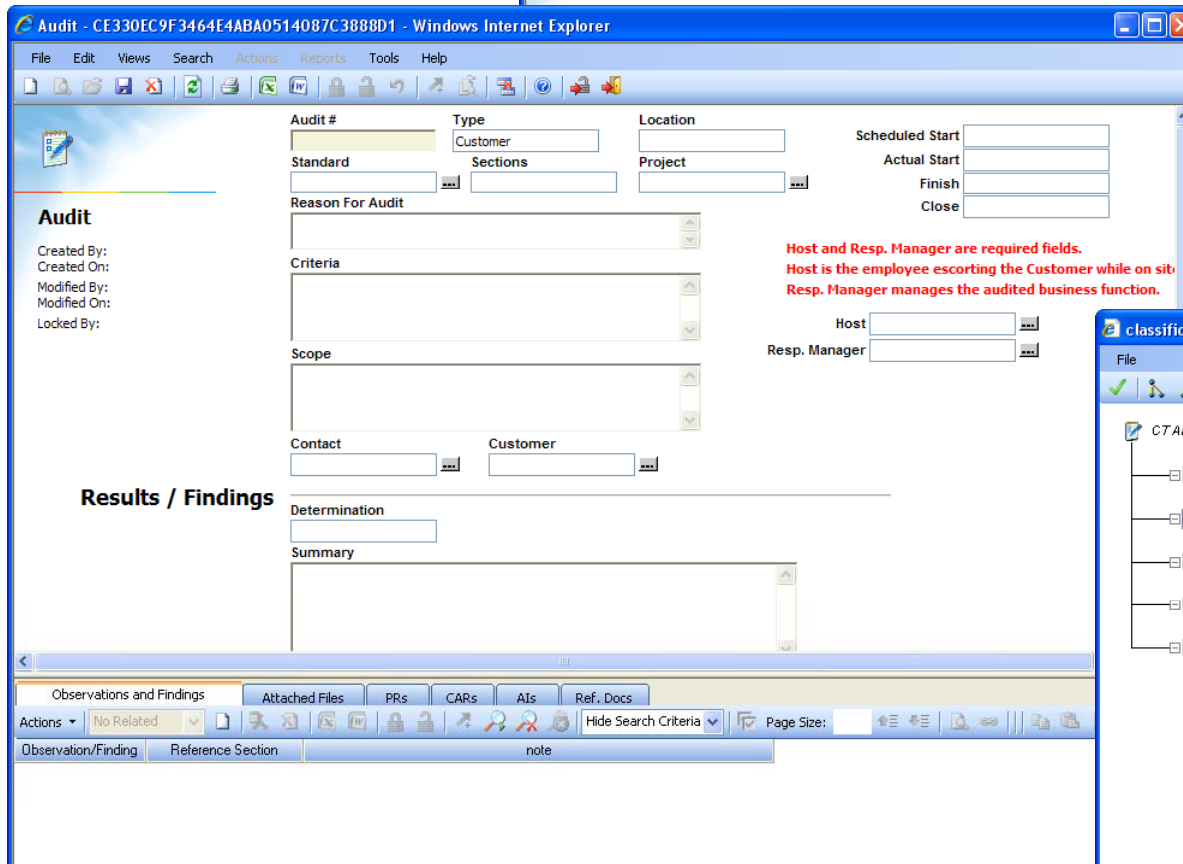
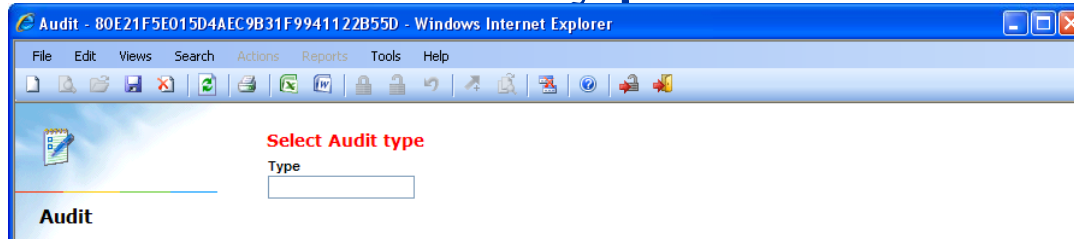
- ❖ How you can leverage existing ItemTypes with classification?
- ❖ Are Non-Conformances, Findings and Observations just PRs of a different class?
- ❖ Are Development or Preventive Action Plans Change Requests of a different class?



Example: Using Innovator in the Quality Loop

- ❖ Customer complaint about Non Compliant Product causes creation of PR (type NCP).
 - ❖ Corrective Action Preventive Action (CAPA) treated as a ECR (change mgt). Structured to meet the ISO requirements – root cause and corrective action planning.
 - ❖ ECN becomes the “Trigger” mechanism initiating and coordinating the corrective action.
 - ❖ Internal audits and/or subsequent product inspections/tests verify the effectiveness of the ECN.
-

Example of Audit ItemType



The Obstacles

- ❖ Misunderstanding ISO
- ❖ Turf issues
- ❖ Competing systems
- ❖ Big Q vs. little q thinking
- ❖ Lack of management involvement

....but worth the effort to overcome these

About Us

Don Stephen is a degreed engineer and owner of Crucis Technology, located in suburban Chicago and founded in 2005. Crucis Technology's primary focus is on planning, implementation and support of Aras Innovator. Prior to launching Crucis Technology, Don held management positions with multinational telecommunications and electronics firms in R&D, Operations and Quality. Crucis Technology can be located on the web at www.crucistechnology.com. Contact Don at don@crucistechnology.com or (630) 839-9136

Maureen McAllister is a CPA and degreed engineer with McAllister Consulting, L.L.C., located in suburban Chicago and founded in 1991. Maureen's consulting practice focuses on compliance and the alignment/integration of compliance activities with other business priorities. Prior to launching McAllister Consulting, she lived and worked in Southeast Asia for a major multinational corporation holding various management positions. She is a published author and guest lecturer. McAllister Consulting can be located on the web at www.mcallister-consulting.com . Contact Ms. McAllister at: maureen602@aol.com or (630) 377-7300.
