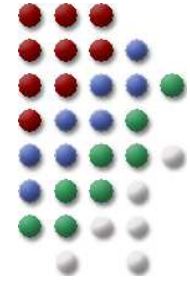
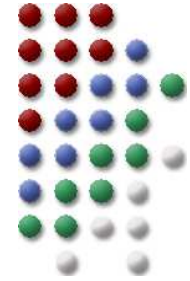


## Current Situation



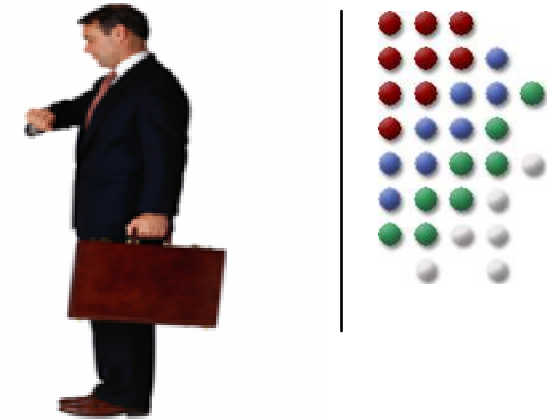
- The ISO 9001:2008 version was released Nov 2008 and the 9004 is in the process of being revised and will not be released until mid 2009
- The ISO 9001 Standard still remains to be the model for business strategies in organizations large and small around the globe
- At the end of 2006, there were nearly 900,000 organizations registered to the ISO 9001 Standard
- Additionally, over 1 million registered to other derivative Standards such as AS 9100, ISO 13485, TL 9000 and TS 16949

## In General the Changes Include:



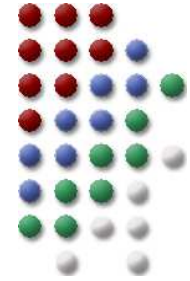
- Mostly, the revisions reflect a closer alignment with the environmental management system International Standard (ISO 14001:2004);
- Clarifying requirements in outsourcing and the addition of more notes to supplement the intentions of the requirements;
- You will see more often the word, “statutory”, along where regulatory was;
- You will notice that in details where record requirements were singled out, now they are combined with document requirements, not to say that 4.2.3 and 4.2.4 were combined;
- Product conformity to requirements has been rephrased in a few of paragraphs;
- “Measuring devices” was called out and now it is more common language to “measuring equipment” in 7.5.1 and throughout 7.6.

## Impact and Timeline of changes



- No additional requirements
- Changes also include numerous guidance notes
- A lot of rewording of several requirements, but no change in the intent
- Therefore, overall the changes are subtle and should not require a significant amount of effort to go ahead and make the changes
- You have 12-18 months to be in compliance, however, the changes to documentation is relatively minor and no additional effort is required to perform audits especially by the registrar

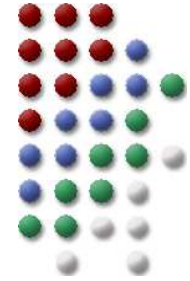
## ISO 9001:2008 / Standard's emphasis remains relatively the same



- Continual improvement
- Increased emphasis of the role of top management
- Defined Now Determine processes
- Consideration of statutory and regulatory requirements
- Establishment of measurable objectives at relevant functions and levels
- Monitoring of information on customer satisfaction as a measure of system performance
- Increased attention to resource availability
- Determination of training effectiveness
- Measurements extended to system, processes and product/service

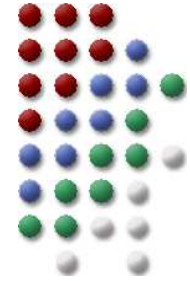


## MSI's Experience with the revised Standard



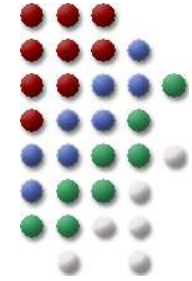
- Those companies pursuing registration were converted to meet 2008 requirements
- MSI has already witnessed a 2008 Preassessment and changes were hardly mentioned. Audit was straight forward
- Many of the documentation requirements were already in existence as a best approach
- MSI has revised and/or is in the midst of changing customers' documentation
- If your company is pursuing registration you have a choice

## Selected from TOP 10 of changes as Significant



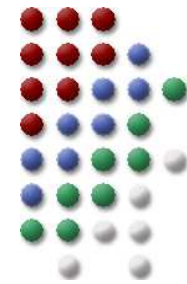
- **Type and Extent of Control for Outsourced Processes (4.1)** Puts more teeth into how outsourced processes are controlled. No more “set it, and forget it” mentality. Active controls are needed.
- **Management Representative as Member of Organization (5.5.2)** Thin ice for some organizations...how far removed can the Management Rep be. Bottom line may be how effective is s/he? (cannot be a person outside of the organization)
- **“Product” isn’t just for Customers any more... (1.1)**  
Emphasizes that “product” should be viewed as that which is required by the customer, or required by the organization for the product realization processes. **Per NQA**

# Changes made to the General Requirements para



## General requirements

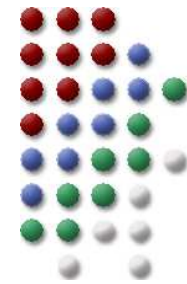
- a), e) an enhancement to the requirement of outsourcing were the changes made to this section.
- For a), instead of identifying processes, now the processes for the QMS are to be determined. This is where the first change from “identify” to “**determine**” was made. “Determine” requires more thought in describing reasons versus “identify” is to recognize a particular need. Determining requires more analysis.
- For e), where applicable, was added after measure, which means you are to monitor processes but it is not necessary to measure processes.



## Cont. of General Requirements

- For the **Outsourcing** paragraph, you will notice a familiar sentence duplicated from the purchasing requirement to **define** the type and extent of control to apply to the outsourced processes.
- Also, outsourced processes, was limited to those processes related to being needed for the QMS such as internal auditing. If MSI performs internal auditing in support of your QMS, we should be on your approved supplier list and will make suggestions as to methods to defining extent and control.



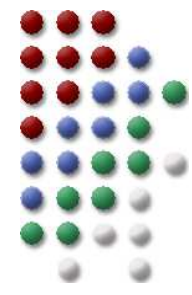


## Changes to Resource Mgmt para

No changes occur until General under Human Resources, 6.2.1, where you will see the verbiage change from product quality to work affecting “conformity to product requirements”. A Note was added to this section to expand on that meeting product requirements could be affected directly or indirectly performing any task.

- 6.2.2 the title was changed to Competence, training and awareness (training now precedes awareness and section a) and b) to the following:
- determine the necessary competence for personnel performing work affecting **conformity to product** requirements,
- **where applicable**, provide training or take other actions to **achieve the necessary competence**

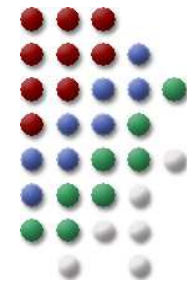
# Infrastructure and Work Environment



- 6.3, Infrastructure, has a minor change to include for information systems, which registrars were already confirming that such systems were established and maintained in order to support the records requirements.



- For 6.4, Work Environment, a note was added to define further that work environment should also include for environmental conditions.

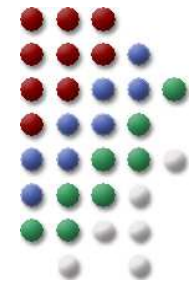


## MSI's Recommendations

- USE the PDCA approach to systematically apply the changes.
- Become acquainted with the changes
  - *Obtain copy of Standard remember to follow updated external document practices*
- Analyze from a documentation impact and implementation
- Develop transition plan (know timeline requirements of your registrar)  
Plan in line with surveillance or initial certification audit
- Communicate the plan including determining training needs to make everyone aware of changes
- Determine actions that need to be taken to implement changes by documentation and procedurally
- Verify effectiveness of actions taken through your internal audit program
  - *Check sheets will need to be revised*



# Use the QMS to drive the changes



- Communicate changes being made
- Manage changes through the QMS (more systematic)
- Revise processes being changed
- Determine responsible persons and authorities
- Train personnel on the changes
- Implement the change
- Perform an Internal Audit to verify effectiveness of changes

