Change Management in ISO QMS

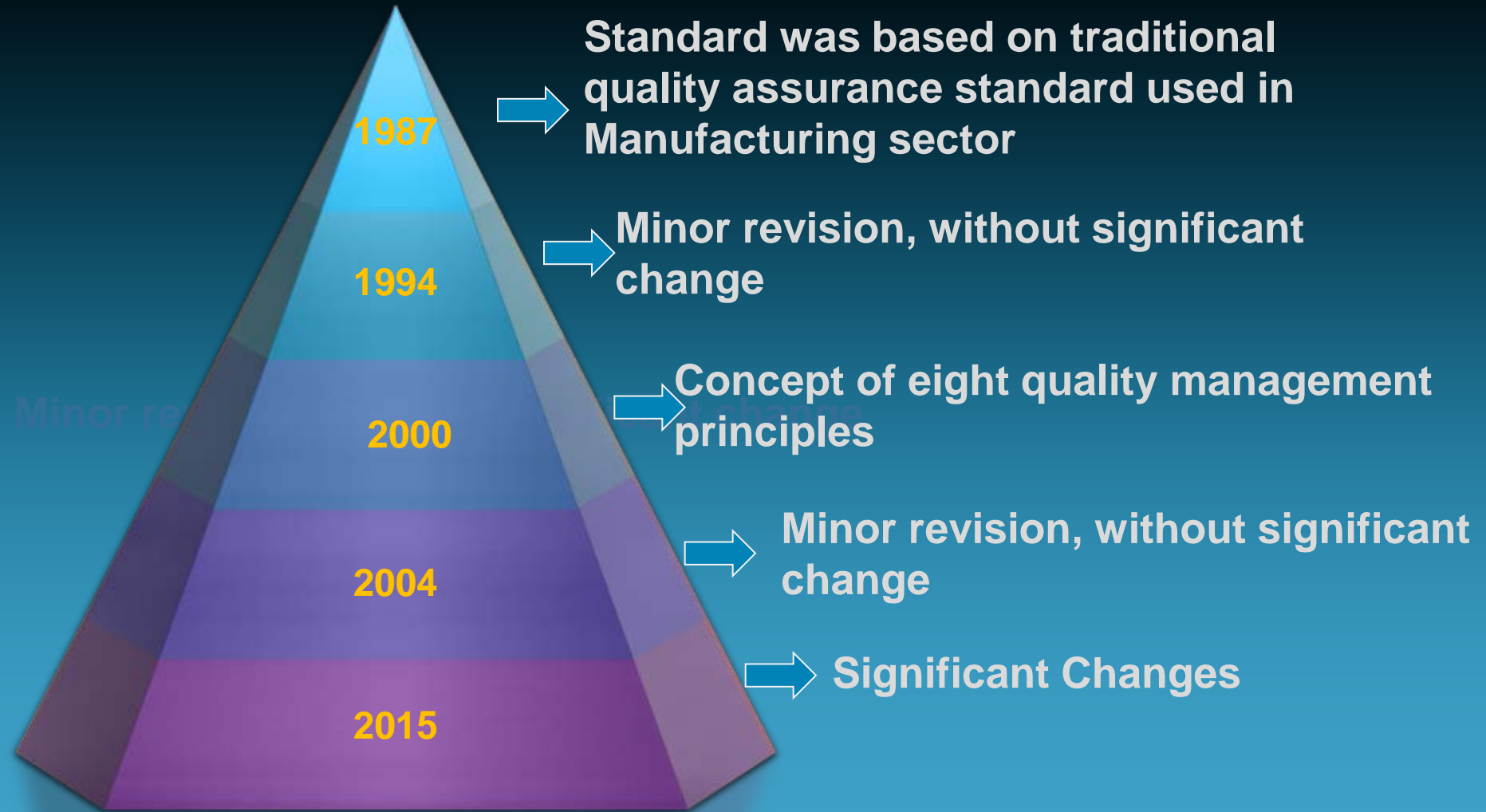## Process and sustainability of good/best practices

Minor revision, without significant change

Alka Jarvis

The Changes to the process of current QMS Development and maintenance methodology are absolutely necessary
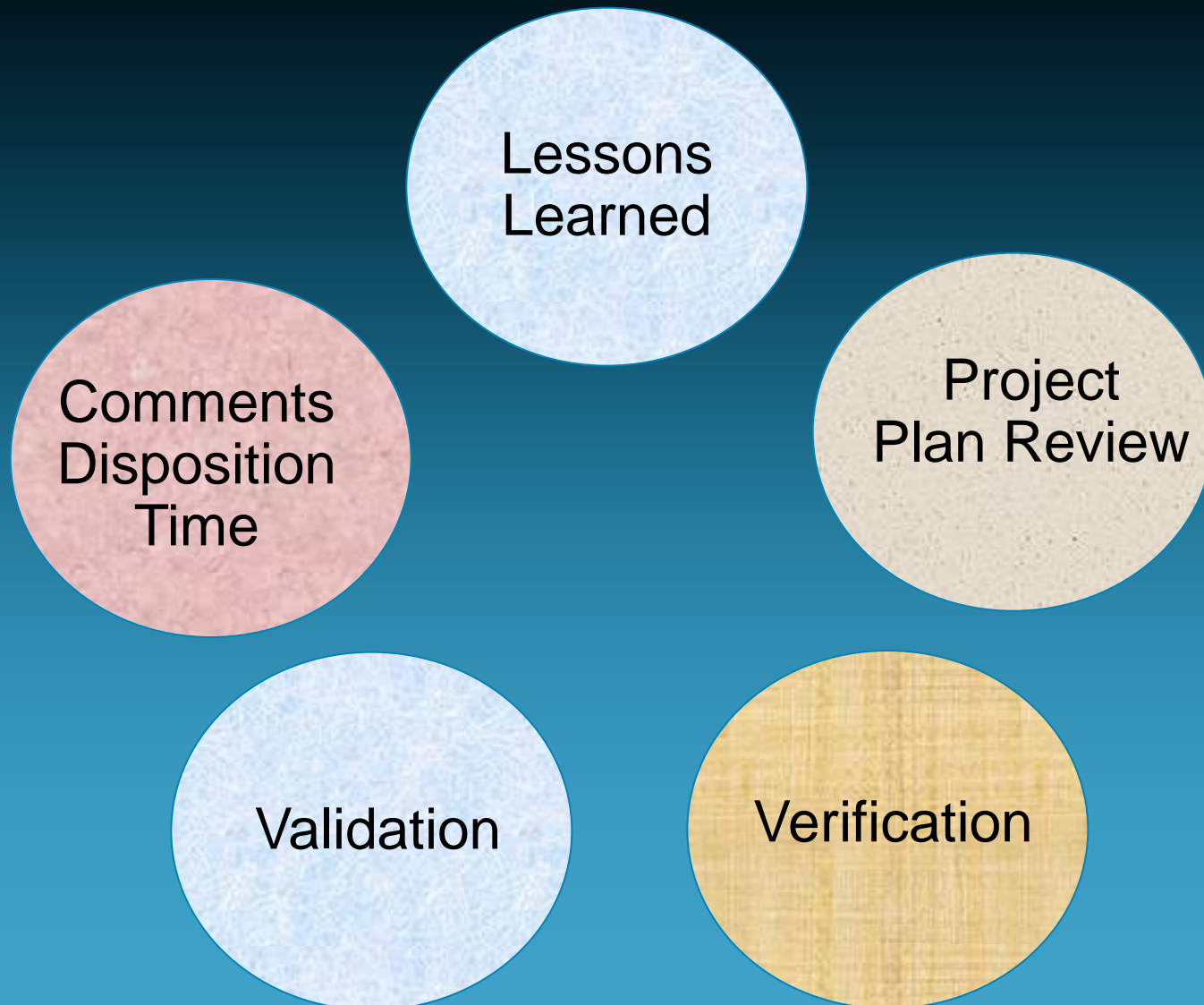
Change

← FAILURE

SUCCESS →

The strategic planning must be done now to maintain the credibility of these Standards

History , Experience and Observations

1987 → **Standard was based on traditional quality assurance standard used in Manufacturing sector**

1994 → **Minor revision, without significant change**

2000 → **Concept of eight quality management principles**

2004 → **Minor revision, without significant change**

2015 → **Significant Changes**

Issues Needing Change

Lessons Learned

Project Plan Review

Comments Disposition Time

Validation

Verification

Best Practices...

Lessons Learned

- **Mandatory entrance criteria for a new project to review and select key lessons for implementation**

- **Should not be allowed to enter into Committee Draft (CD) stage, without evidence of adherence**

- **Deviations to the above, to be signed by SC2 Chair, Secretary, Convener and Deputy, with risk assessment and mitigation plan developed by the convener**

Best Practices…

Project Plan & Review

- **Initial overall project plan to be reviewed by SC2 Chair and agreed upon by all stakeholders**

- **Status review of the project plan during each opening and closing SC2/WG plenary**

- **No short-cuts in all the steps listed, allowed**

- **Delay communicated in advance to the ISO secretariat**

Best Practices…

Verification

- **Evidence: all input documents outlined in the design document were considered**

- **Verification results reviewed and joint consensus between SC2 Chair, Secretary, WG/TG Convener**

Best Practices…

Validation

- **Validation report taken seriously, every comment dispositioned adequately**

- **Response to national bodies how validation comments were dispositioned**

- **TC176/SC2 Chair and Secretary cannot make decision, without Validation WG/TG convener and co-convener agreement**

Best Practices…

Comments Disposition Time

- **Allow adequate time to disposition comments received during CD phase (s). Catch any shortages during Project Plan review**

- **Include the validation comment dispositioning step in the project plan**

- **No short-cuts allowed!!!**

Sustainability

- **Convener training**
  - A checklist of items that must be met prior to starting the project

- **Ensure schedule adjustments are made, as needed**

  In closing plenary, discuss moving forward strategy after time adjustments are made

- **Frequent communications**

  Internal
  - All workgroups
  - ISO Secretariat
  - Any other dependent Standard (s)

  External
  - Users
  - Media

- Hold individuals accountable for deviations to the process

US/Columbia Collaboration

- **Partner on issues**

- **Periodic status meetings to discuss concerns/issues**

- **Consensus on methodology to address concerns/issues**

- **Joint discussion on pros/cons on suggestions/recommendations**

- **Provide support during internal WG/TG meetings**

Change Management and implementation of best practices

will be a

Continuous, rewarding journey for the QMS Family of Standards, ISO 9000, 9001, 9004