

Fermilab CD QA As-Is Assessment Overview



Bakul Banerjee
Computing Division
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Integrated Quality Assurance Program Objectives



- ⌘ **Foster an environment of continuous improvement**
- ⌘ **Implement improvements in identified areas**
- ⌘ **Satisfy the commitments made in the FRA contract proposal**
- ⌘ **Achieve compliance with DOE Order 414.1C, Quality Assurance**

As-is Assessment Objectives (1)



- ⌘ **Develop a hierarchical list of the more significant work processes within CD**
- ⌘ **Identify best practices and existing quality controls**
 - ☑ **Get credit for QA we're already doing in the division**
- ⌘ **Identify differences (or gaps) between “as-is” and required quality controls using IQA criteria**
- ⌘ **Contribute to the Lab-wide review of the following 4 areas of risk**
 - 1. Inspection, test and control of measuring & test equipment (M&TE)**
 - 2. Managing qualification and training**
 - 3. Item control**
 - 4. Control of documents and records**

As-is Assessment Objectives (2)



- ⌘ **Evaluate compliance of scientific research to ANSI/ASQ Z1.13**
 - ☒ **Comparison of scientific research to “Quality Guidelines for Scientific Research at Fermilab” (under development)**
- ⌘ **Document assessment results in a systematic manner**
- ⌘ **Develop Corrective Action Plans to bridge gaps between “as-is” and “as-required” conditions.**
- ⌘ **Exclusion: QA of software development life cycle**

Definitions in the Context of the QA Assessment



⌘ CD Activities:

- ☒ **“What” goods and services we provide; “what” we are doing.**
- ☒ **Defined in our budget and planning processes.**

⌘ CD Work Processes:

- ☒ **“How” we provide those goods and services; “how” we intend to accomplish our work.**
- ☒ **Some activities may have many processes; others may not.**

⌘ Procedures:

- ☒ **Written description of the process steps.**

⌘ Controls:

- ☒ **Steps in a process that apply control to the output**

How To - As-Is Assessment in CD

For each functional area, each individual activity assessment will be conducted by a team made up of the Activity Owner, QAR (in assistance role) and QAE (in advisory role).

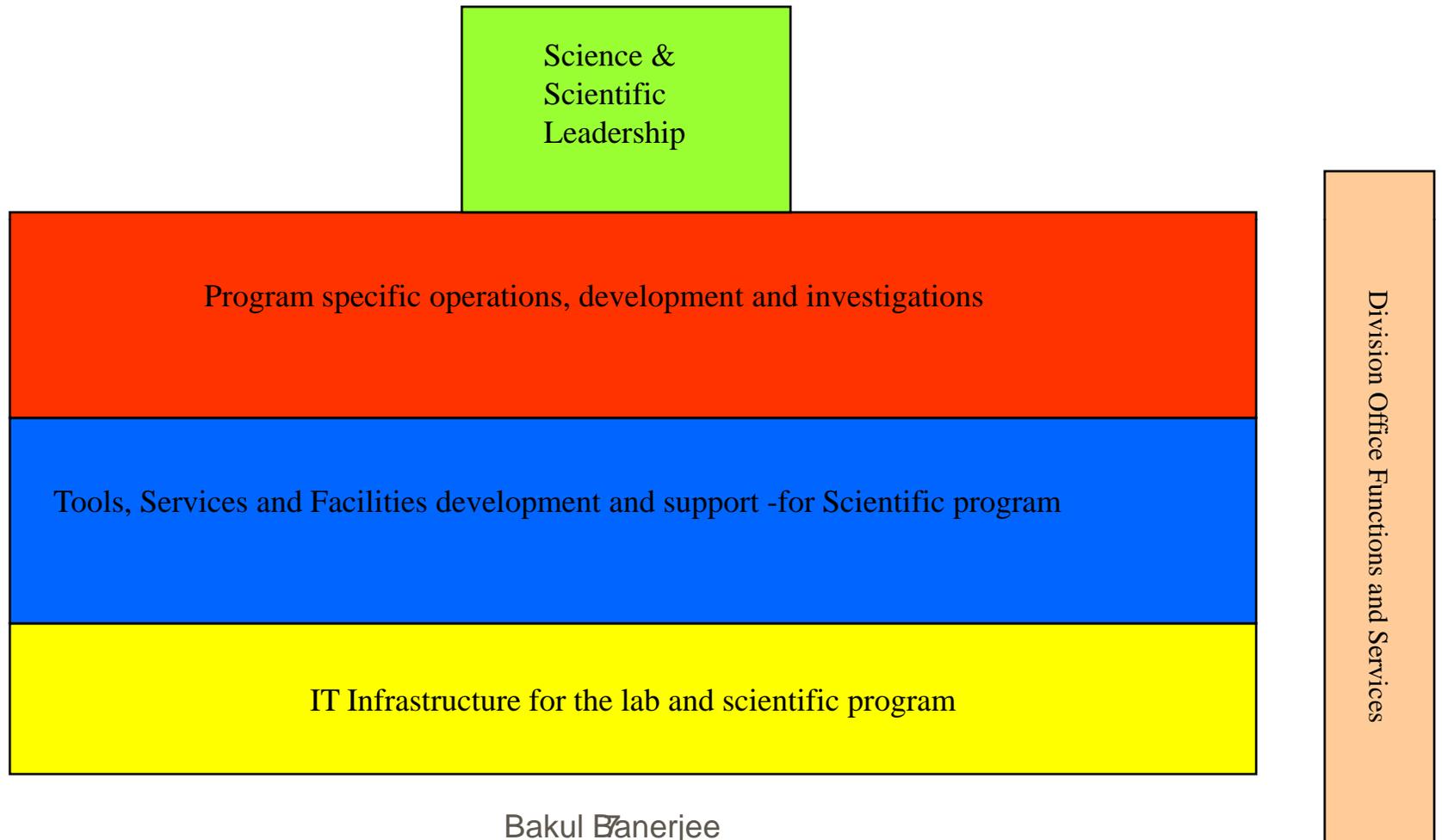
The format of the assessment is as follows:

1. Identify representative CD work processes to be assessed (beginning at the highest levels).
2. Review procedures associated with these work processes
3. Determine applicable IQA criteria for these procedures
4. Identify and document presence or absence of controls

Assessment rules:

- ☒ No judgment; just document the controls that exist for each criterion
- ☒ Get credit for controls in place. Get credits for best and noteworthy practices (e.g. ITIL/ ISO 20000 Alignment)
- ☒ Assess areas that may benefit with an independent closer looks
- ☒ Only a sample of processes will be assessed

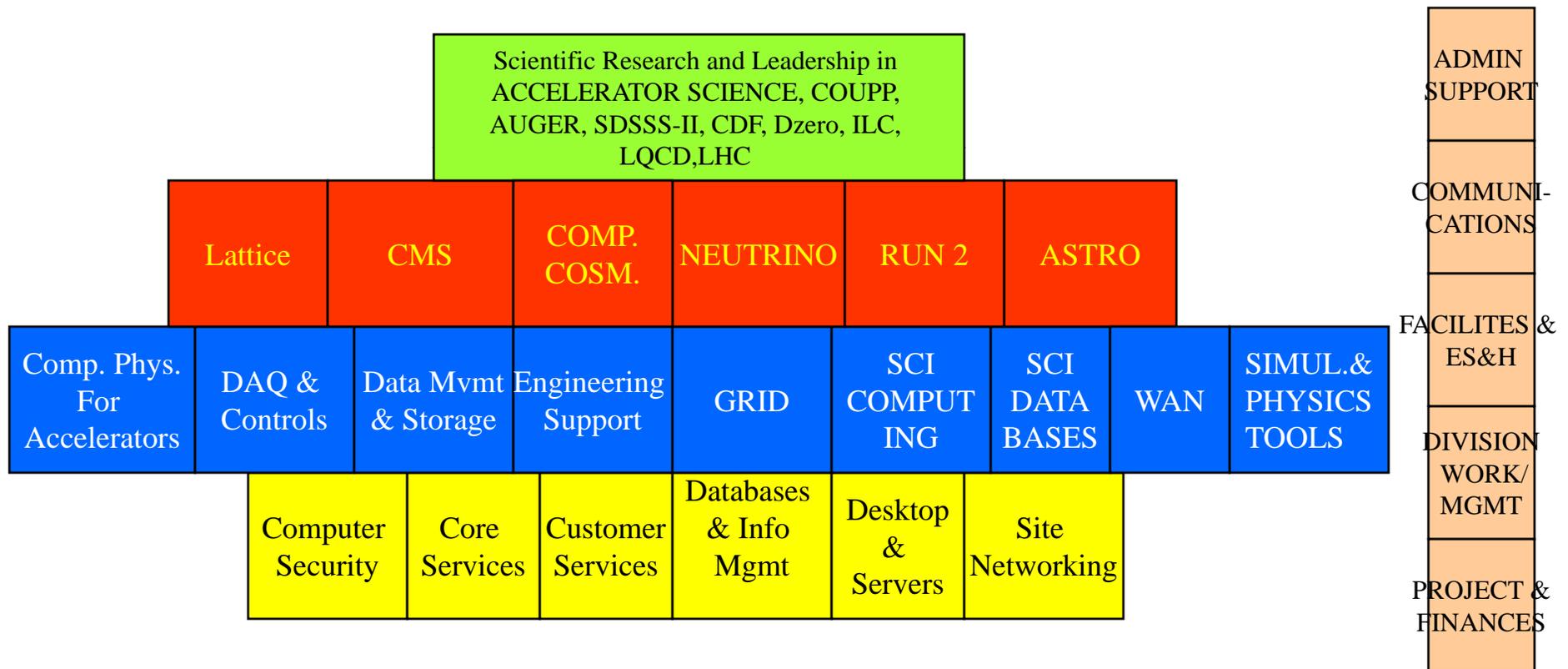
Assessment Approach: Align with CD Work Organized by Layers



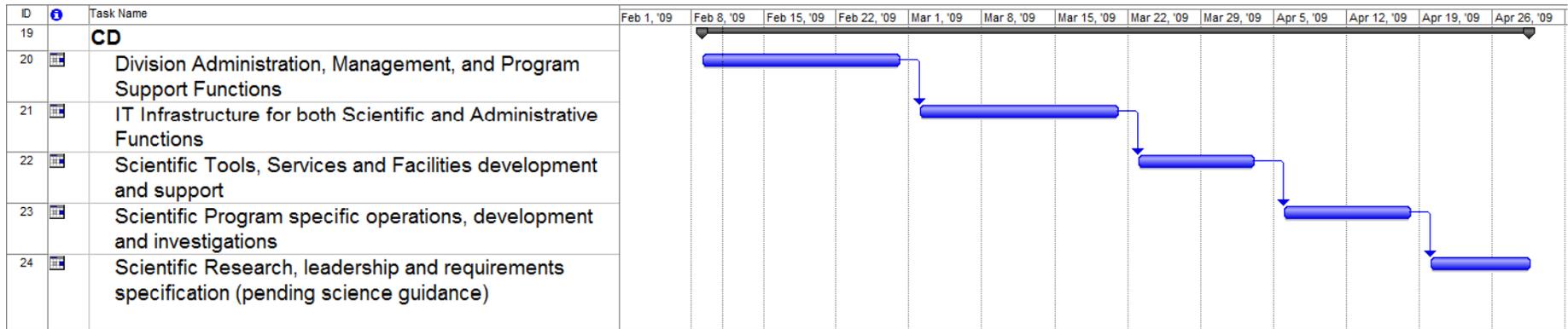
Bakul Banerjee

CD Activities Organized by Layers

(From V. White's Budget Presentation)



Planned CD Assessment Timeline (Adjustable)



IQA Criteria (Additional Slide)



- ⌘ Criterion 1 Program
- ⌘ Criterion 2 Personnel Training and Qualifications
- ⌘ Criterion 3 Quality Improvement
- ⌘ Criterion 4 Documents and Records
- ⌘ Criterion 5 Work Processes
- ⌘ Criterion 6 Design
- ⌘ Criterion 7 Procurement
- ⌘ Criterion 8 Inspection and Acceptance Testing
- ⌘ Criterion 9 Assessment
- ⌘ Suspect/Counterfeit Items (S/CI)
- ⌘ Scientific Research (ANSI/ASQ Z1.13-1999)

Background (Additional Slide)

- ⌘ Directorate/EG&G QA Team – after new FRA contract
- ⌘ Two major guidance documents:
 - ☑ Integrated Quality Assurance (IQA) – Approved by DOE Chicago Office 11/7/08
 - ☑ Graded Approach Procedure for Quality Assurance
- ⌘ Quality Assurance Representative (QARs) for D/S/C assigned – 10/20/08
- ⌘ As-Is Assessment as described in Directors Corner (1/27/09) – Begins 2/2/09 ending 4/30/08
- ⌘ Upcoming DOE QA Audit – September 2009
- ⌘ More: <http://www.fnal.gov/directorate/OQBP/Index.htm>

Guidance Documents (Additional Slide)

- ⌘ Integrated Quality Assurance program (IQA)
- ⌘ Graded Approach Procedure
- ⌘ Fermilab Integrated Contractor Assurance Program (FICAP)
- ⌘ Suspect/Counterfeit Items Program

References:

- ⌘ Director's Corner Article in Fermilab Today 1/27/09
- ⌘ Director's Policy Manual
http://www.fnal.gov/directorate/Policy_Manual.html
- ⌘ Fermilab Work Smart set of standards & FESHM standards
- ⌘ DOE 2006 QA Audit Report for Fermilab
- ⌘ DOE O 414.1C Quality Assurance
- ⌘ ANSI/ASQ Z1.13 for research:
<http://tdserver1.fnal.gov/project/standards/ANSI-ASQ-Z1-13.pdf>
- ⌘ DOE G 414.1-3 S/CI Guide