CRADA Order Revision

Linda Field
Patent Counsel
Department of Energy

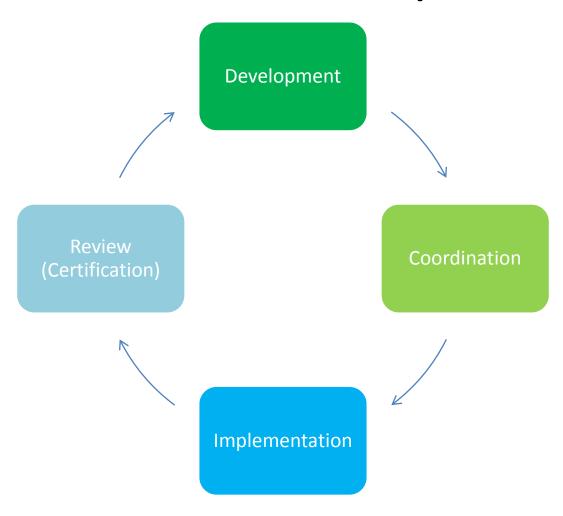
Goal



Departmental Directive Program Types of Directives

Policies Regulations **Orders Notices Manuals** Guides **Technical Standards**

Departmental Directive Program Directives Life Cycle



Development Phase

- Orders are uploaded to RevCom for review and comment by all affected parties
- •60 days to develop draft & submit to MA-90
- •Solicits input from stakeholders (incl. field, contractors, and/or program counsel)

Coordination Phase

- •MA-90 parses directive & sets due dates for review & comment
- HQ Directives Points of Contact (DPCs)
 - Have 45 days to submit official comments on behalf of their organization
 - Consolidate comments within organization (incl. field offices)
 - •Have 30 days to respond to all official comments on RevCom (Comment Resolution)
- •MA-90 posts 2nd draft directive on RevCom for concurrence
- Commenters (Subject Matter Expert) concur or non-concur
- •DPC have 15 days to consolidate concurrence/non-concurrence on 2nd draft
- Writer & opposing party resolve issues, inform MA-90
- •Writer prepares final draft, submits to MA-90, then DRB

Coordination (Cont)

- MA-1 engages the DRB members and senior mgt of opposing organizations to facilitate resolution of unresolved issues.
- If resolution cannot be reached, then approval memo is rewritten to include the issue, contending organization, office of primary interest positions and DRB's recommendation
- Secretary or Deputy Secretary renders decision

Implementation

- HQ DPCs and Field DPCs are notified when directive is approved.
- Field DPCs notify CO/CORs
- CO/CORs determine if applicable to contractor
- If contractor agrees, impact assessment then implementation plan

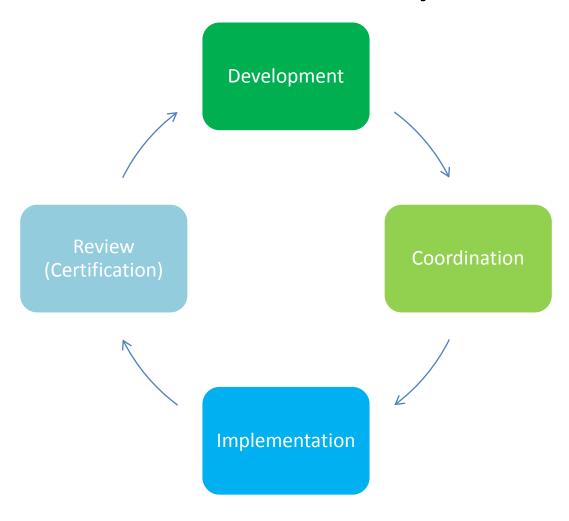
Review (Certification)

- MA -90 publishes list of directives up for review
- Office of Primary Interest (OPI) reviews directive to determine if to certify, revise or cancel
- If OPI decides to certify, then submit memo to MA-90
- MA-90 submits memo to DRB for approval
- If approve, the directive in effect for 4 yrs

Review (Certification) cont'd (OPI and MA-90)

- If OPI decides revise or cancel, then submit memo to MA-90
- MA-90 submits memo to DRB for approval
- If DRB agrees to cancel directive, memo is posted on RevCom for 30 days, commenters can concur or reject cancellation
- DRB makes final decision on cancellation of directive
- If DRB concurs on revising directive, then...

Departmental Directive Program Directives Life Cycle



PRE-RevCom

 Review Order and Manual and solicit comments from field, labs and TTWG (reformatting no small task)

 Prepare new draft order and model CRADA(s) and circulate

Prepare final draft for RevCom and submit

Issues

- CRADA Approval Process
- Short Form CRADA
- Protected Data
- Subcontractor access to proprietary data
- U.S. Competitiveness
- Advance Payment