

Date: 06Nov2017

To: Cook Inc. CAP Project Management Office

From: Kate Duncan, Cook Inc. CAP 1.10 Training Workstream Lead

Subject: Cancellation of Protocol_CAP011, Change Request Training Compliance

Protocol

Cc: CINC CAP 1.10 Training CAP file

Protocol_CAP011 was initiated as part of Cook Inc. CAP 1.10 Training Workstream to address gap 1.10-3d (i.e, Inconsistent/inadequate training for Change Request process). The purpose is to establish a pilot program for the evaluation of training needs related to the Change Control process. All training associated with approved Change Requests was to be considered within the scope of this pilot program. The Cook Inc. CAP for 1.10 reported the need for a plan under item 21.4 of Cook Inc. Training CAP Detail quarterly report, see table below:

CAP Item	Action	Resp Person	Due Date	Expected Deliverable	Status (Comments)
21.4	Change Request Training Compliance Protocol	Team	See Below	Protocol_CAP0 11	In Process
21.4.1	Develop and approve Protocol_CAP011	Team	TBD	Approved Protocol	In Process
21.4.2	Execute and write report for Protocol_CAP011	Team	TBD	Executed Protocol and Report	Not Started

The protocol was drafted but was never routed for approval. Upon further review of the purpose and scope of the proposed Change Request Training protocol, the team decided to cancel protocol CAP011 based on the fact that identification of training needs will be driven by the implementation of QSP35. Quality Plan QP071 (1.10 Training Workstream Future State Implementation) has been initiated to define the phased approach for implementation of QSP35 procedures and a pilot plan was not considered necessary as part of this process. Other issues that influence the decision were:

- Gap 1.10-3d is a medium risk gap and the future state process under QSP35,
 Competency and Training, will address the gap.
- IT improvements to the Learning Management System (LMS) are required and the improvements are planned for completion by the "go live" date of QSP35, *Competency and Training* procedures.