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The formulae $\frac{\partial \rho \bar{U}_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{U}_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ *for building* $\frac{\partial}{\partial x_j}(\rho \bar{U}_i \bar{U}_j)=-\frac{\partial \bar{P}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{U}_i}{\partial x_j}-\rho \overline{u_i' u_j'}\right)+g_i(\rho-\rho_0)$ *state of the art* $\frac{\partial}{\partial x_i}(\rho \bar{U}_i \bar{H})=\frac{\partial}{\partial x_i}\left(\lambda \frac{\partial \bar{T}}{\partial x_i}-\rho \overline{u_i' h'}\right)$ *biomedical research facilities.*

APF Closeout Documentation

Documentation is an essential part of Aseptic Processing Facility (APF) project development. Proper documentation is required to establish and maintain an efficient and compliant APF. This documentation provides evidence that the facility systems and equipment are designed, constructed, commissioned, qualified, validated, and maintained in a state of compliance in order to meet the current Good Manufacturing Practice (cGMP) requirements identified in 21 CFR Parts 210 & 211. Good Documentation Practices (GDP) should be followed throughout the process of developing, finalizing, and maintaining critical documents to ensure the quality of documentation meets cGMP requirements.

Project Closeout

The project "closeout" or "turnover" documents include all facility documentation that is approved after all project activities are concluded. A more detailed description of the Project Closeout and Handover phase is described in Section 13.18.0 of the Design Requirement Manual (DRM). Well organized and timely delivery of the closeout documents is expected from the responsible parties; to facilitate this delivery, a document process flow should be communicated early in the project to all parties involved which reviews the preparation, closeout, and maintenance of documents. The project documentation requirements must be clearly defined, along with the roles and responsibilities of all parties involved in developing, maintaining, and revising project documents. The Facilities Compliance and Inspection Section (FCIS) under the Division of Technical Resources (DTR) has created a Standard Operating Procedure (DTR-SOP-10021) for managing facility turnover documents.

The following are examples of typical documents that are developed throughout the various phases of a project (documents to be maintained as current for the life cycle of the community are underlined):

- **Planning Phase:** Facility Risk Assessment (FRA), Statement of Requirement (SOR), and Feasibility Study (FS)
- **Design Phase:** Quality Risk Management Report (QRM), Facility User Requirement Specifications (URS), Validation Mater Plan (VMP), GxP Harmonization Report, Basis of Design (BOD), Design Qualification (DQ), System Level Impact Assessment (SLIA), Design Drawings, and Design Specifications
- **Construction Phase:** Executed VMP protocols, such as Factory Acceptance Test (FAT), Site Acceptance Test (SAT), Testing and Balancing Report (TAB), Construction Submittals, Redline Drawings and Specifications
- **CQV Phase:** Component Level Impact Assessment (CLIA), Executed VMP Protocols, such as Installation Qualification (IQ), Operational Qualification (OQ), Airflow Visualization Study (AVS), Training Documents and Records
- **Hand-Over Phase:** Record Drawings and Specifications, Commissioning Report, Qualification Report, and Validation Report

Roles and Responsibilities

FCIS is responsible for collecting, tracking, controlling, and maintaining the critical facility documents identified in DRM Table 13.18.0.

The NIH **Project Officer** (PO) should coordinate with the contracted organizations (i.e., A/E, CM, CQV) to ensure timely delivery of APF turnover documents at the close of each phase. The PO identifies each applicable document to be included within the Scope of Work for each phase of the project. The PO also ensures that each turnover document is reviewed and approved by the applicable personnel prior to delivering documents to FCIS. It is highly encouraged that a document management specialist should be assigned to each group responsible for the closeout documents in order to manage the flow of documents throughout the project.

The FCIS **Document Management Specialist** (DMS) coordinates the project turnover document requirements with the PO to ensure the proper management, control, and delivery of documents at the end of each phase. Depending on the document type, the delivery of these critical documents should be either in an electronic format or both in electronic and hard copy with the original signature approval sheets for selected documents. Upon delivery of turnover documents, the FCIS DMS will store all electronic documents in a shared folder directory and a SharePoint site. All critical documents are stored in a secure location managed and controlled by the FCIS DMS.

Conclusion

Good communication and coordination are essential when managing the flow and progress of critical facility documents for a project closeout. Tools such as SOPs, flow diagrams, and document matrices will assist in the timely and accurate delivery of these documents by all parties throughout the project. It is essential to establish an early understanding of the document closeout process with all participants, because a team effort is necessary for the success of APF project document management.

'Design Requirements Manual (DRM) News to Use' is a monthly ORF publication featuring salient technical information that should be applied to the design of NIH biomedical research laboratories and animal facilities. NIH Project Officers, A/E's and other consultants to the NIH, who develop intramural, extramural and American Recovery and Reinvestment Act (ARRA) projects will benefit from 'News to Use'. **Please address questions or comments to:** shawm@nih.gov

Further details on this month's topic are available on the DRM website: DRM Section 13.18.0
https://www.orf.od.nih.gov/TechnicalResources/Pages/DesignRequirementsManual2016.aspx