REVIEW OF SUBMISSIONS IN THE SUBMISSION TRACKING AND REPORTING SYSTEM (STARS) QUEUE

I. PURPOSE

This document states the office policy on reviewing submissions based on their due date in the Submission Tracking and Reporting System (STARS) queue, describes how the policy is implemented, and describes how exceptions to the policy are handled.

Management of the submission queue should allow for (1) completion of the review of a sponsor's submission within the established STARS due date, (2) equitable processing of sponsors' submissions, and (3) efficient use of reviewers' time. The intent of this document is not to impede established review management practices that meet these goals.

II. HOW TO REVIEW ACCORDING TO THE QUEUE

The responsibility for "reviewing according to the queue", or in order of the due dates in STARS, resides primarily with the individual reviewer, not at the Office, division, or even team level. Reviewers are responsible for managing their individual queue. Reviewers ensure that they allocate sufficient time for evaluation of each submission while completing other tasks assigned to them. The team leader and division director are responsible for the queue in the organizational unit and may reassign submissions to balance the workload or to ensure a timely review and closing out of a submission.

As a reviewer, you will generally complete the substantive review of each pending submission in the order of the assigned STARS due date. Because the complexity of submissions and the review timeframes vary by submission type, completing assigned STARS submissions on time will likely require a reviewer to simultaneously work on multiple submissions in their queue in order to meet all deadlines. Note that administrative tasks, such as evaluating newly assigned submissions[1] and completing the final action process for submissions currently in the queue for administrative reasons,[2] are not part of this policy.

When you are assigned a submission in STARS, you should determine the purpose of the submission or if you are assigned a consulting review, you should read and make sure you understand the instructions from the primary reviewer found in Appian.[3] Depending on the submission type or request from the primary reviewer, you may

[1] See P&P 1243.2050 and P&P 1243.3100
[2] See P&P 1243.3029 and 1243.3030
[3] Refer to Section VII of the Appian User Guide on to Access Documents in Appian

need to review items out of queue to ensure that the final action will be completed by the STARS due date if further administrative actions are needed prior to completion (e.g., concurrence from consulting reviewers or a Quality Control Review from the Quality Assurance Team is needed[4]). Additionally, for some submissions or applications there is a multistep clearance and sign-off chain that involves individuals in different divisions or at the office and/or center level that requires additional time in order to finish by the STARS due date.

Meeting minutes may be completed earlier than the STARS due date to ensure that the minutes are recorded accurately and to allow attendees to review and concur on the documents. The procedures for preparing a memorandum of conference are outlined in P&P 1243.3025.

Examples of unacceptable queue management include: 1) ignoring overdue submissions while completing other submissions, 2) postponing the review of a difficult submission while completing other submissions, and 3) allowing a submission to go overdue, while completing a submission with a later STARS due date.

III. MANAGEMENT APPROVAL TO PERMIT EXCEPTION TO REVIEWING ACCORDING TO THE QUEUE

A. Exceptions Requiring Team Leader or Division Director Approval

There may be submissions where there are administrative reasons for reviewing a submission out of queue (e.g., Good Manufacturing Practice (GMP) status check, or voiding a submission[5]). In these situations, concurrence by a team leader or division director is sufficient.

In some situations, you may need to review items out of queue if submissions are associated with another submission (e.g., Bioresearch Monitoring (BIMO) inspection report[6] and a sponsor's response to an inspection report). If submissions are related in such a way that reviewing them concurrently, even if they have different STARS due dates, will lead to a better or more complete scientific decision, consult with your team leader or division director. If they agree, then conduct the substantive review of the submissions together. You will document in the review the reason for completing the review out of order and document any relevant discussion and decisions made by your team leader or division director. You should complete the review of related submissions by the earliest STARS due date.

B. Exceptions Requiring Office Director and/or Center Director Approval

While CVM does not have an expedited review process, there may be an infrequent occasion where an application or submission needs to be reviewed and completed ahead of other submissions in a reviewer's queue. The directive to review these submissions ahead of other items in the queue generally come from either the Office Director or Center Director. Some examples of circumstances that

[4] See P&P 1243.3210
[5] See P&P 1243.8500 and 1243.3011
[6] See P&P 1243.8225

require possible exception to reviewing according to the queue that require Office Director and/or Center Director approval include reviewing submissions related to pending legal proceedings, animal drug shortages for medically necessary veterinary products,[7] or other emergency situations. In these cases, you will need written approval from the Office Director and/or the Center Director. To obtain this approval, your division director should speak with the Office Director, who will determine, in conversations with the Center Director, what level of approval is required and the steps necessary to obtain that approval. The reviewer will document the reason the submission has been reviewed out of order and any relevant communication with the Office Director and/or Center Director in the review.

IV. REFERENCES

CVM Program Policy and Procedures Manual

1240.4170 – CVM Medically Necessary Veterinary Drug Product Shortage Management

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.2050 – Refuse to File and Refuse to Review

1243.3011 – Voiding Submissions and Discontinuing the Review of Pending Submissions and Applications

1243.3025 – Preparing a Meeting Documentation (i.e., Memorandum of Conference, Acknowledgment Letter, Other Review Documentation)

1243.3029 – Closing Out Consulting Reviews for Submission Tracking and Reporting System (STARS) Submissions

1243.3030 – Completing Final Action Packages for Submission Tracking and Reporting System (STARS) Submissions

1243.3100 – ONADE Refuse to Review (RTR) and Refuse to File (RTF) Assessment of Submissions and Applications that Contain Data

1243.3210 – Requesting a Quality Control Review from the Quality Assurance Team for Final Action Packages Signed by the Office or Center Director

1243.8225 – Review of Bioresearch Monitoring (BIMO) Establishment Inspection Reports (EIRS)

1243.8500 – Making a Request for a Current Good Manufacturing Practice (CGMP) Status for an Approval Package

[7] See P&P 1240.4170

V. VERSION HISTORY

December 3, 2002 – Original version

January 23, 2009 – Revised to include concepts related to the end-review amendment process and how end-review amendments impact queue order, remove information on expedited review, make minor editorial changes and update format.

August 20, 2018 – Revised to remove end-review amendment process and make editorial changes and update format to new P&P template. Also updated process described in section III B. from written Center Director approval to Office Director and/or Center Director approval and direct the reviewer to document authorization within the review.

December 14, 2018 – Revised to correct typographical errors.

May 6, 2021 – Revised to update P&P titles in the Reference section. Added language in section II that reminds reviewers that instructions to consulting reviewers can be found in Appian.