Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

DOCUMENT NUMBER: COMM-PAS-029

DOCUMENT TITLE:
Management Review and Responsibility

DOCUMENT NOTES:

Document Information

Revision: 01	**Vault:** COMM-PAS-rel
Status: Release	**Document Type:** COMM-PAS

Date Information

Creation Date: 20 Jun 2025	**Release Date:** 01 Jul 2025
Effective Date: 01 Jul 2025	**Expiration Date:**

Control Information

Author: MC363	**Owner:** MC363
Previous Number: None	**Change Number:** PAS-CCR-043

COMM-PAS-029
Management Review and Responsibility

1 PURPOSE

1.1 This Standard Operating Procedure (SOP) provides an overview of how management reviews the quality management systems (QMS) for the Adult and Pediatric Blood and Marrow Transplant Program (APBMT) and Stem Cell Laboratory (STCL).

2 INTRODUCTION

2.1 This procedure outlines how management reviews the quality systems to ensure continuing adequacy, suitability, and effectiveness, and to evaluate the need for changes to the systems at planned intervals. Management reviews are also used to identify and assess opportunities to change quality policy and quality objectives to address resource needs and to look for opportunities to improve products.

2.2 The QMS should be adequate and capable of satisfying applicable requirements, including those specified by the organization, the customer, and any applicable standards and/or regulations.

3 SCOPE AND RESPONSIBILITIES

3.1 This SOP applies to all members of management, including Program and Facility Medical Directors, Program and Facility Managers, Duke Cancer Institute (DCI) leadership, and the APBMT Clinical Quality Program (CQP) in APBMT and STCL with responsibilities related to the QMS.

3.2 The Management Representative(s), who could be the Program and/or Facility Medical Director and/or Manager, communicate with applicable staff, as needed, regarding scheduled reviews. They are also responsible for any assigned reviews and/or sign-offs on reports and/or minutes, if applicable.

3.3 The CQP facilitates the development, implementation, and maintenance of effective QMS. They also provide and compile data related to the QMS, as needed, for the management representative's reviews. The CQP reviews and signs off on reports and/or minutes, if applicable.

4 DEFINITIONS/ACRONYMS

4.1	APBMT	Adult and Pediatric Blood and Marrow Transplant Program
4.2	CAP	College of American Pathologists
4.3	CLIA	Clinical Laboratory Improvement Amendments
4.4	CQP	APBMT Clinical Quality Program
4.5	CRS	Cytokine Release Syndrome
4.6	DCI	Duke Cancer Institute
4.7	DCS	Document Control System

4.8 EFS Event Free Survival

4.9 FACT Foundation for the Accreditation of Cellular Therapy

4.10 FDA Food and Drug Administration

4.11 GvHD Graft versus Host Disease

4.12 QA Quality Assurance

4.13 QMP Quality Management Plan

4.14 Quality Management System (QMS): Set of interrelated or interacting elements used to direct and control how quality policies are implemented and quality objectives are achieved.

4.15 SOP Standard Operating Procedure

4.16 STCL Stem Cell Laboratory

4.17 TRM Treatment-Related, Non-Relapsed Mortality

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Computer Access

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 General

8.1.1 Program and/or Facility Medical Director(s) review information at multiple time points throughout the year. These reviews are done via quarterly reports and/or through an annual process.

8.1.2 At a minimum, the CQP and the Program and/or Facility Medical Director(s) will document these reviews through signed reports and/or meeting minutes.

8.1.3 Should corrective or preventive actions result, these action items will be documented in MasterControl (MC) per COMM-PAS-015 *Corrective and Preventive Actions*.

8.1.4 It is the ultimate responsibility of the Management Representative(s) or designee to ensure that action items are addressed and that the in-place processes and systems are functioning appropriately.

8.2 Adult and Pediatric Blood and Marrow Transplant Program (APBMT)

8.2.1 APBMT is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). The program reviews its clinical quality indicators in quarterly meetings with the APBMT and Cellular Therapy

Quality Assurance (QA) Committee, which is comprised of a multidisciplinary group, including the Program and Facility Director(s), Program and Facility Managers, DCI leadership, CQP, and key personnel.

8.2.2 The following clinical inputs are reviewed:

Clinical (at defined time points):

Time to engraftment

Central venous catheter infections

Acute and chronic Graft versus Host Disease (GvHD)

Overall mortality and survival

Treatment-related, non-relapse mortality (TRM)

Incidence and Endpoints of Cytokine Release Syndrome (CRS)

Incidence and Endpoints of Neurotoxicity

Event Free Survival (EFS)

8.3 Stem Cell Laboratory (STCL)

8.3.1 The STCL program is accredited by FACT, College of American Pathologists (CAP), and is a processing facility for APBMT. The STCL also has a Clinical Laboratory Improvement Amendments (CLIA) certification. Similarly to APBMT, the facility inputs are reviewed at quarterly meetings.

8.4 APBMT & STCL

8.4.1 The APBMT and Cellular Therapy QA Committee review and report on the following non-clinical inputs at the quarterly meetings.

8.4.2 The following inputs are reviewed:

Facilities

Equipment Management

Inventory Control/Supply Management

Document Control/Records Management

Event Management

Process Management and Control

CQP Audits and Supported Inspections

8.4.3 The quarterly meetings are documented with meeting minutes, which are reviewed and signed by the Co-chair(s) of the APBMT and Cellular Therapy QA Committee, Program and Facility Medical Directors, and members of the CQP.

8.4.4 The CQP provides annual summary reports on the performance of the Quality Management Plan (QMP) to the APBMT and Cellular Therapy

QA Committee. The annual summary reports are reviewed and signed by the Program and Facility Medical Director(s) and members of the CQP.

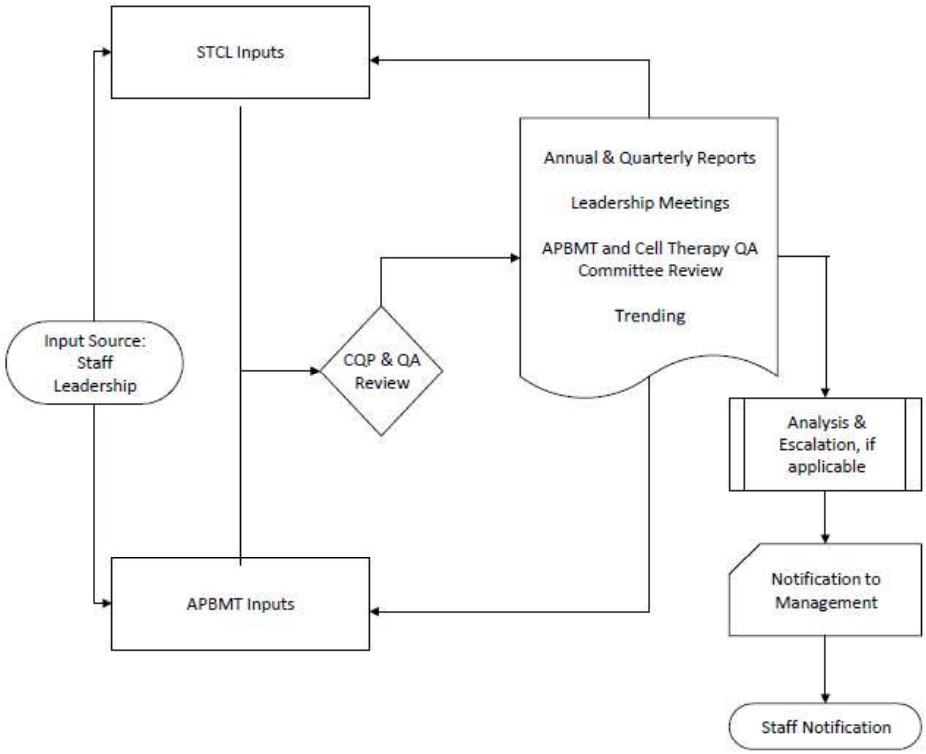
8.4.5 It is expected that the Management Representative(s) in these meetings will disseminate information from the quarterly meetings and annual reports to applicable staff.

8.4.6 Conversely, it is expected that the applicable staff will alert the appropriate Management Representative(s) of concerns in the program/facility, and the Management Representative(s) will bring those concerns to the meetings for discussion.

8.4.7 Flowchart #1 illustrates the flow of reporting information within APBMT and STCL.

APBMT and STCL
Data Reporting Flowchart

Flowchart #1



COMM-PAS-029 Flowchart #1
APBMT Clinical Quality Program (CQP)

Page 1 of 1

9 RELATED DOCUMENTS/FORMS

9.1 APBMT-COMM-027 Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan

9.2 COMM-PAS-015 Corrective and Preventive Actions

9.3 STCL-QA-006 Stem Cell Laboratory Quality Management Plan

10 REFERENCES

10.1 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Current Edition

10.2 FACT Common Standards, Current Edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	New document

Signature Manifest

Document Number: COMM-PAS-029 **Revision:** 01
Title: Management Review and Responsibility
Effective Date: 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-028 -- COMM-PAS-036

Author

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 12:02:28 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Kris Mahadeo (KM193)		26 Jun 2025, 10:32:36 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Kris Mahadeo (KM193)		26 Jun 2025, 10:33:03 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 05:14:37 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:54:47 PM	Approved