CLINICAL PATHOLOGY DEPARTMENT

National Cancer Institute
Cairo University

QUALITY MANUAL

NCI –CPD-QAU-QM-01

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TABLE OF CONTENTS

The Quality Manual.

The Quality Manual describes the Quality Management System of the Clinical Pathology Department Laboratories (CPD Labs)
Throughout the text there are references to "Medical Laboratories - Requirements for Quality and Competence ISO 15189:2012 Standards" (bracketed in red) and to CPD Labs policies and procedures (bracketed in blue), that are written to meet the Standards.

The Quality Manual fulfils two functions:

- It describes the Quality Management System for the benefit of the Laboratory's own management and staff (4.2)
- It provides information for users and for accreditation and inspection bodies.

The Quality Manual can be regarded as the index volume to separate manuals of management, laboratory, clinical and quality procedures.
The sections of the Quality Manual are arranged so that they provide statements to describe how the Laboratory complies with ISO 15189:2012 Standards:

Section of Quality Manual	**Section of ISO 15189: 2012 Standards**
4	Section 4 Management Requirements
5	Section 5 Technical Requirements

Under the title of each Standard is a brief description of the way in which the Clinical Pathology Department Laboratories seek to comply with the particular Standard and references to appropriate procedures are cited.
The Quality Management System and the examination processes are continually evaluated and quality assured by internal and external audit and review (4.14). The results of audits are used to maintain and improve the Quality Management System, meet the needs and requirements of service users and continually improve (4.12)

1.0 Introduction

The Clinical Pathology Department was established as a part of National Cancer Institute to provide clinical testing services for all patients, using the most recent standard techniques and methods. Establishment of National Cancer Institute was based on the presidential decree number 278 dated 1981.
Clinical Pathology Department includes 9 units; Hematology laboratory unit, Microbiology laboratory unit, Chemistry laboratory unit, Immunology laboratory unit, Bone marrow transplantation laboratory lab. unit, Blood Bank laboratory unit, Intensive care laboratory

unit, Sampling laboratory unit in Adults Outpatient Clinic and Sampling Laboratory unit in Pediatric Outpatient clinic.

The accrediation project includes Bone marrow transplantation laboratory unit and Haematology laboratory unit.
The scope of Bone Marrow Transplanataion Laboratory Unit activities are:

1. Flow cytometry laboratory
2. Molecular biology laboratry
3. Immunogenetics laboratory

The scope of Haematology Laboratory Unit activities are:

1. Haematomorphology laboratory
2. Coagulation laboratory
3. Bone marrow aspirate and bone marrow biopsy laboratory
4. Cytochemistry laboratory
5. Cytogenetics laboratory
6. Immunohistochemistry laboratory

The laboratories developed their work to meet customer needs,and expectation, applicable regulatory requirements and comply with the requirements of the international standard ISO 15189: 2012.

This manual describes our compliance with this international standard.

It is prepared by the Quality Manager, and approved by Head of Clinical Pathology Department and Dean of National Cancer Institute

The starting date for implementation is the issue date of the manual & procedures.

Any amendment in the manual will be according to the document, data and records control procedure (NCI-CPD-QAU-QP 001).

1.1 Laboratory Vision

Clinical Pathology Department Laboratory Units

1.1.1 Our Vision:

Clinical Pathology Department Laboratories will provide the highest quality laboratory testing in oncology, institutionally and nationally. We will be the national reference laboratories and gain international recognition.

رؤيتنا:
تقوم معامل قسم الباثولوجيا الإكلينيكية بتوفير أعلى مستوى من جودة الإختبارات المعملية فى مجال الأورام محلياً ودولياً. نسعى أن نصبح المعامل المرجعية على المستوى القومى ونحظى بالإعتراف الدولى

1.2 Laboratory Mission

Clinical Pathology Department Laboratory Units

Mission

Our mission is to provide education and training for young doctors to achieve postgraduate degrees, nationally and regionally, to conduct scientific research and participate in scientific conferences, both nationally and internationally, to provide accurate and timely precised laboratory services to contribute to excellent patient healthcare and to improve healthcare provided to patients through compliance with international accreditation standards

رسالتنا:
رسالتنا هى توفير التعليم والتدريب للأطباء الشباب للحصول على درجات الدراسات العليا محلياً وإقليمياً وإجراء البحث العلمي والمشاركة في المؤتمرات العلمية على المستويين المحلى والدولي وتقديم خدمات معملية دقيقة ومحددة التوقيت للمساهمة في الرعاية الصحية المتميزة للمرضى والإرتقاء بمستوى الخدمة الطبية المقدمة للمرضى من خلال الإلتزام بمعايير الإعتماد الدولية

1.2.1 BMT Lab Unit Mission

The mission of the Bone Marrow Transplantation Laboratory Unit (BMT Lab Unit) is to provide routine, research educational and training services in the advanced laboratory techniques namely Flow Cytometry, Molecular Genetics, and Immunogenetics. It is the national referral laboratory in Flow Cytometry with a very wide panel of application, and also in immunogenetics for choice of donors and follow up of recipients of allogeneic BMT. It receives samples from the governmental and university hospitals. The unit is involved in several national and international research projects.

رسالة معمل وحدة زرع النخاع:

تعمل وحدة زرع النخاع المعملية على توفير التحاليل الروتينية للمرضى وإجراء الأبحاث مع إتاحة خدمة التعليم والتدريب في مجال التحاليل المعملية المتقدمة وهى التدفق الخلوي، الدراسة الجزيئية للجينات، المناعة الجزيئية والدراسة الجزيئية المتعلقة بالأدوية العلاجية. ويقدم معمل التدفق الخلوي أنواعا كثيرة من التحاليل ليس فقط لمرضى المعهد ولكن على المستوى القومي. ويقوم معمل المناعة الجزيئية بنفس الدور في مجال اختيار المتبرع لعملية زرع النخاع ومتابعة المرضى بعد الزرع. وتستقبل الوحدة طلبات تحاليل في هذه المجالات من وزارة الصحة والمستشفيات الجامعية. وتشارك الوحدة في العديد من المشروعات البحثية على المستويين القومي والعالم

1.2.2 Hematology Lab Unit Mission

Provision of clinical laboratory services for cancer patient with haematological diseases through the following test services, Hematomorphology laboratory, Coagulation laboratory, Bone marrow aspirate and bone marrow biopsy laboratory, Cytochemistry laboratory, Cytogenetics laboratory, and Immunohistochemistry laboratory

رسالة معمل وحدة أمراض الدم:

تقديم خدمة لمريض سرطان الدم لتشخيص المرض من خلال عمل التحاليل الآتية: تحاليل صور الدم الكاملة ، تحاليل تجلط الدم ، فحص عينات النخاع العظمى وكيمياء الأنسجة المناعية ، فحص عينات النخاع العظمى مع كيمياء الخلية وتحليل سائل النخاع الشوكى و تحاليل الوراثيات الخلوية،، الكروموزومات والجينات المسببة للأورام.

1.3 Laboratory Quality Policy

Clinical Pathology Department Laboratory Unit

Clinical Pathology Department Laboratory Units provide medical testing services for ensuring the highest quality that meets customer needs and expectation.

The management and personnel are committed to:

1. Compliance with the international standard ISO 15189: 2012
2. Compliance with Good laboratory Practice “GLP” and ethical conduct.
3. Compliance with ministry of health (MOH) laws and regulations.
4. Commitment to health and safety of all laboratory staff, patients and visitors.
5. Using the latest techniques to provide the highest achievable quality of all tests performed.
6. Ensuring the competency of laboratory staff and continuous education.
7. Continual improvement in lab performance according to requirements of ISO 15189: 2012.
8. Collection, transport and handling of all samples are performed by means that preserve sample integrity and to ensure correct performance of laboratory examinations.
9. Performing quality activities to assure integrity, accuracy, precision, reliability, and timelines of the data.
10. Participating in external quality assessment programs.

Approval

Head of Clinical Pathology Department

Prof. Dr. Nayera El Shakankiry

1.4 Clinical Pathology Department Laboratory Units

- LAYOUT

1.4.1 Bone Marrow Transplantation Laboratory Unit Layout (attached)

1.4.2 Hematology Lab Layout (attached)

1.5 Clinical Pathology Department Laboratory Units Organization charts (attached)

1.5.1 NCI organization Chart (attached) **F-NCI-CPD-QAU-QM002/02-1**

1.5.2 Clinical pathology Organization chart (attached)

F-NCI-CPD-QAU-QM002/02-2

1.5.3 BMT Laboratory Unit Organization Chart (attached with names)

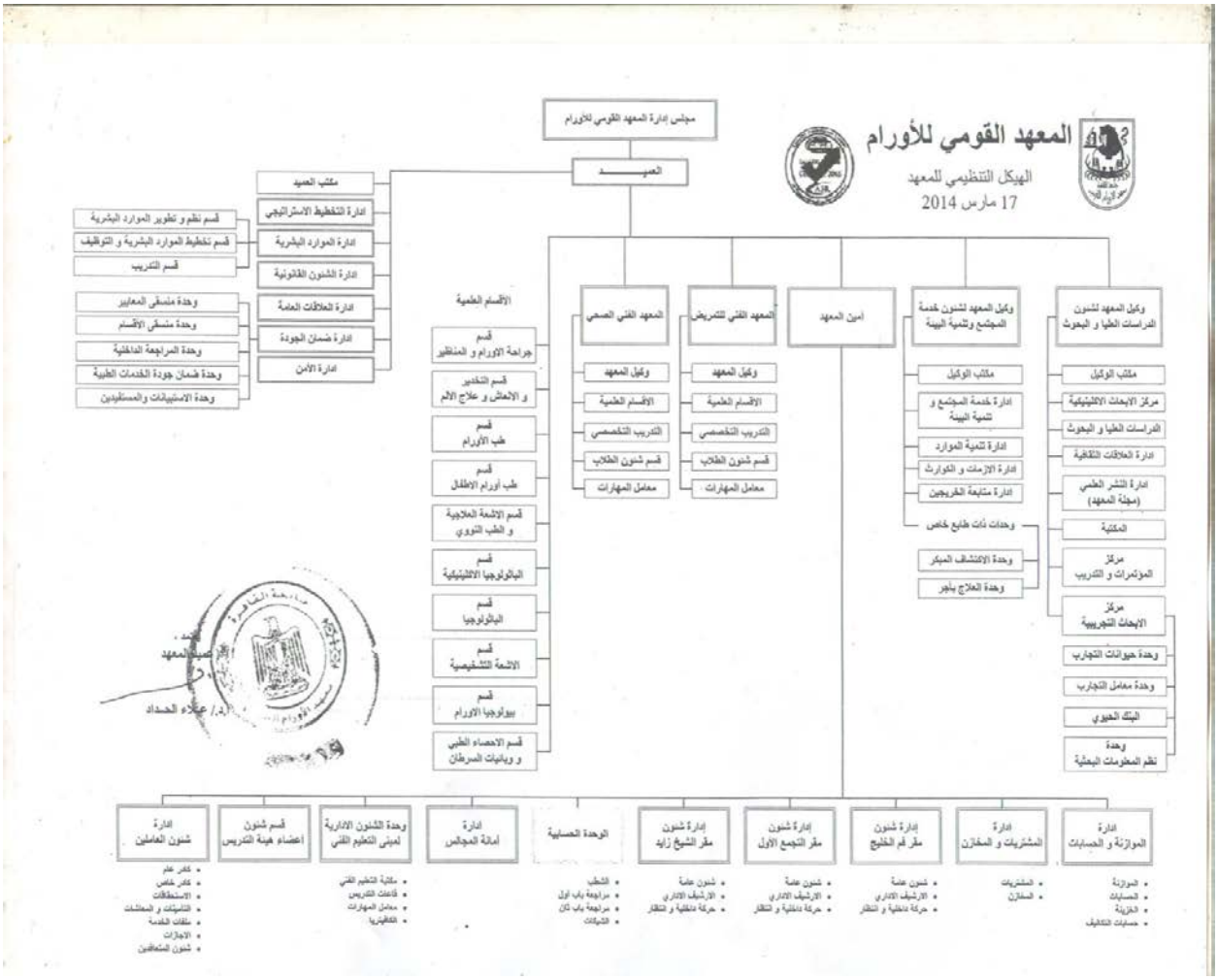
F-NCI-CPD-QAU-QM002/02-3

1.5.4 Haematology Laboratory Unit Organization Chart (attached with names)

F-NCI-CPD-QAU-QM002/02-4

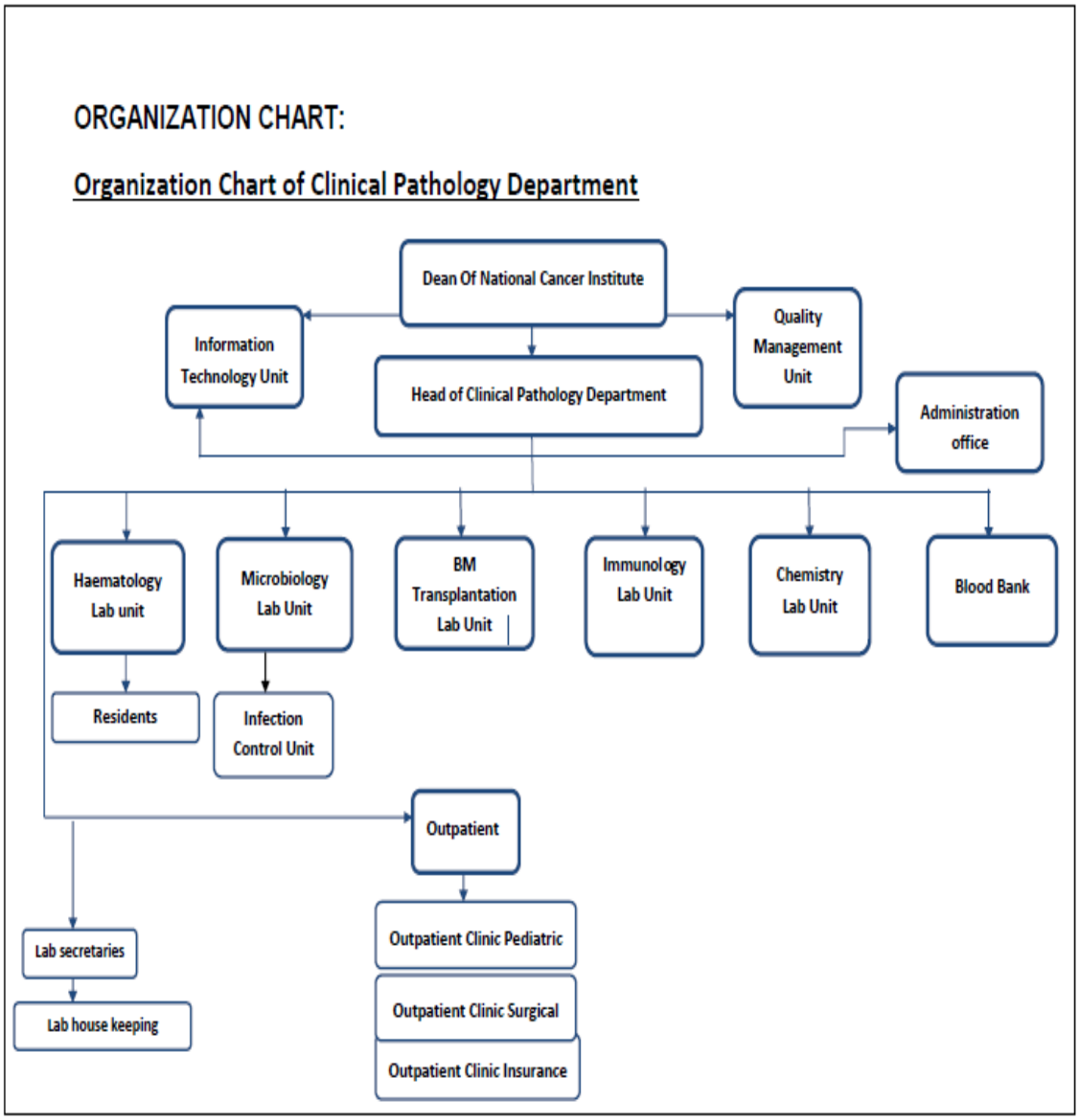
1.5.1 NCI organization Chart (attached)

F-NCI-CPD-QAU-QM002/02-1

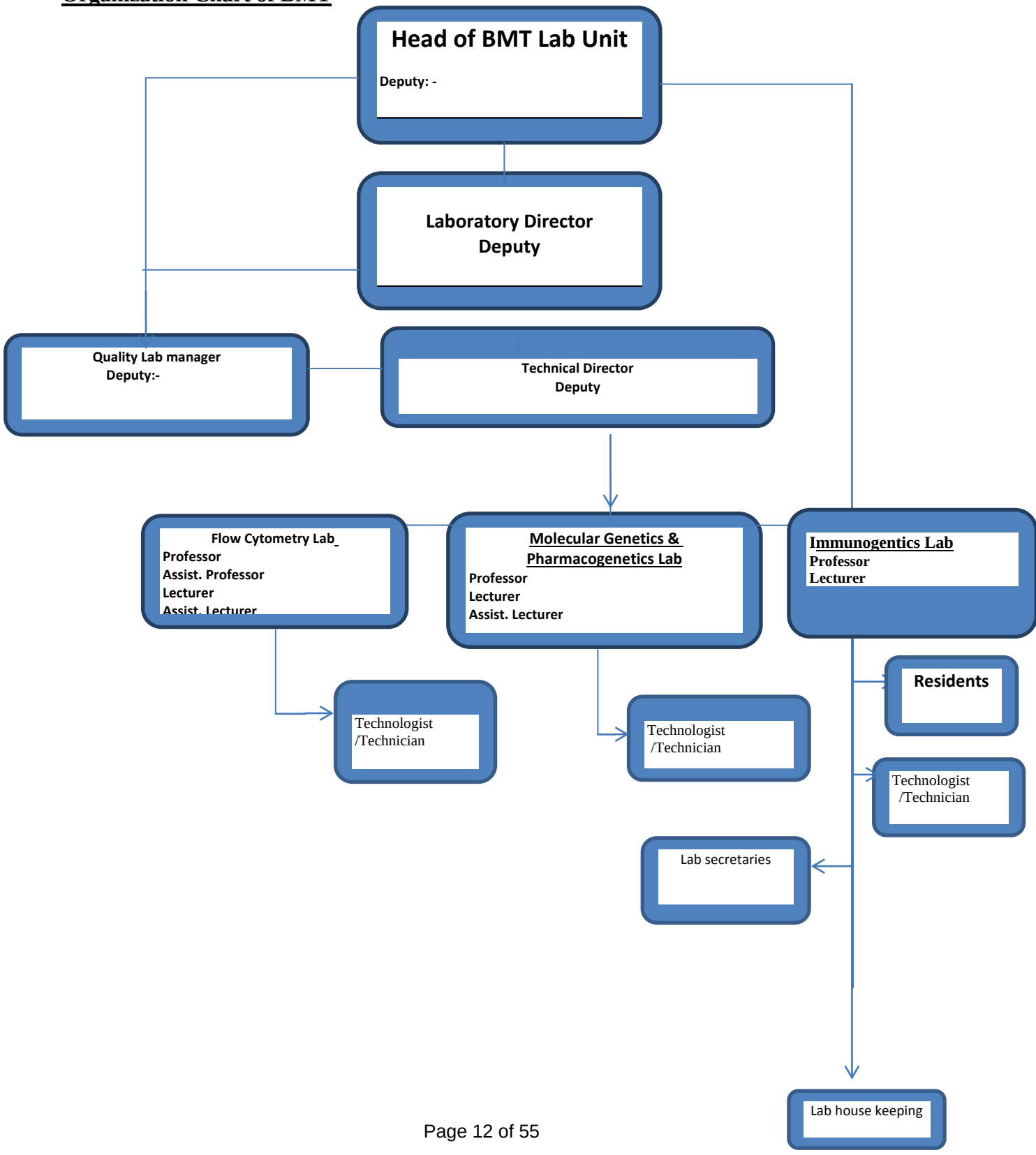


1.5.2 Clinical patholog Organization chart

F-NCI-CPD-QAU-QM002/02-2

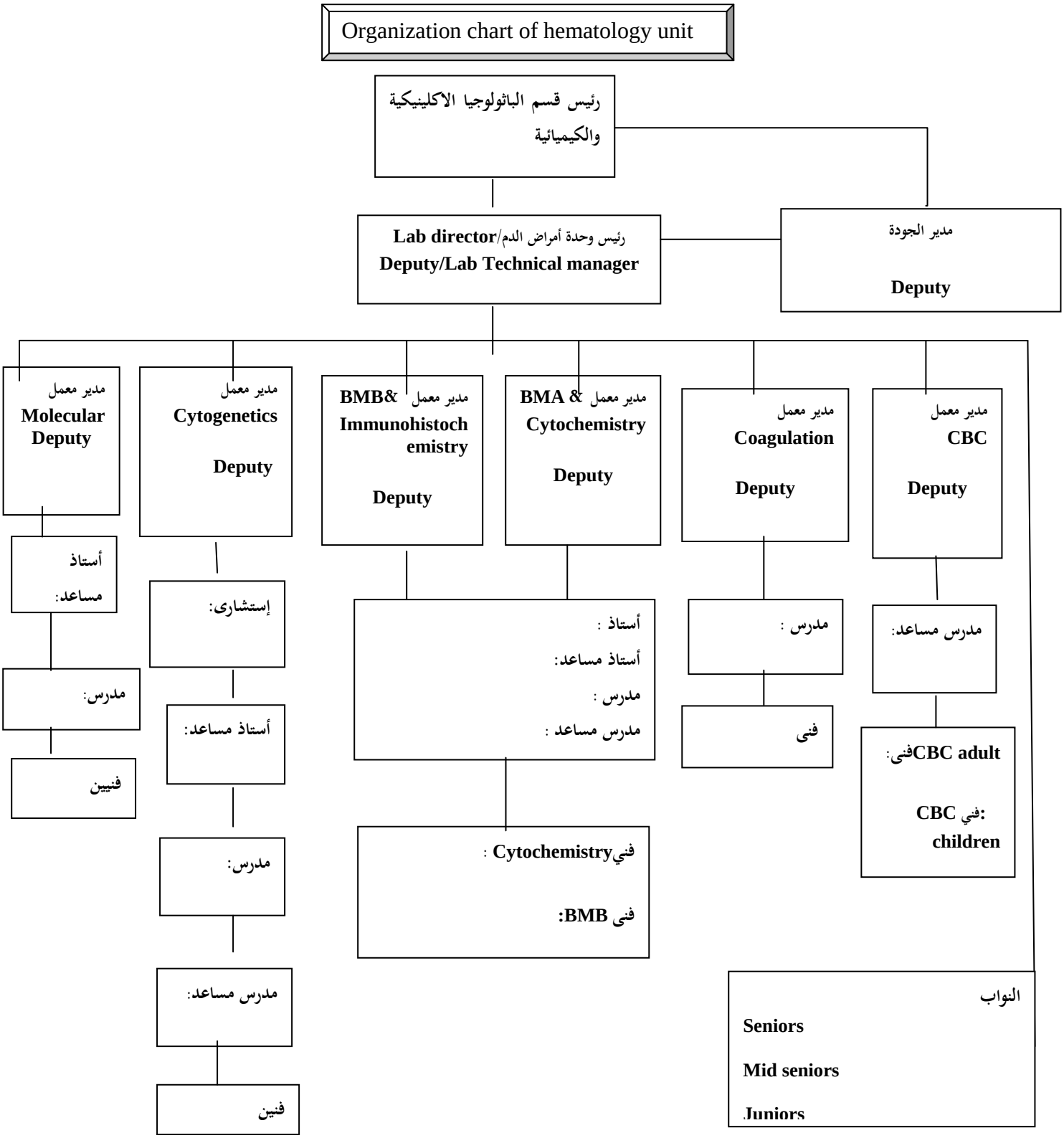


Organization Chart of BMT



1.5.4 Haematology Laboratory Unit Organization Chart:

F-NCI-CPD-QAU-QM002/02-4



1.6 LABORATORY LOCATION

- **Address: Kasr El-Eini Street- Fom El Khalig-Cairo- Egypt**
- **Telephone : 00202 23689 711**
- **Fax : 002 02 23644 720**
- **Post. code: 11796**
- **E-Mail : nci@nci.cu.edu.eg**
- **Contact Person: Prof. Dr. Amira Soliman**
- **Web-site: www.nci.cu.edu.eg**

Reference: Clause (4.1& 4.2) ISO 15189:2012

2.0 Scope of Accreditation:

- For BMT and HEM Lab Units (attached)

3.0 List of Equipment

- For BMT and HEM Lab Units (attached)

4- Management requirements:

4.1.1 Organization

- The Clinical Pathology Department is part of National Cancer Institute, Cairo University. It is legally identified to provide medical laboratory services, which meet the requirements of International Standard ISO 15189: 2012 and satisfy the needs of the client and the regulatory authorities.
- Laboratory management system covers work carried out in the laboratory's permanent facilities. (The lab. has no temporary or mobile facilities).
- The responsibilities of key personnel in Clinical Pathology Department who have an involvement or influence on testing activities carried out by the laboratory units are defined in order to identify potential conflicts of interest.
- The laboratory units have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and to initiate actions to prevent or minimize such departures .
- Arrangements are applied to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work .
- The organizational and management structure is established as shown in the Organisation Charts (Refer to Clinical Pathology Department Organization Charts 1.5), its place and the relationship between quality management, technical operations and support services.
- The lab organisation chart and job descriptions clarify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests.
- The Lab manager provides adequate supervision for technical staff, including trainees, and introduces the methods and procedures, purpose of each test and the assessment of the test results and has overall responsibilities for the technical operations

- The Lab Manager has appointed a quality manager with a defined responsibility and authority for ensuring that the quality system is implemented and followed at all times as well as with direct access to Clinical Pathology Department management where decisions are made on laboratory policy or resources.
- Clinical Pathology Department Laboratory Unit managers have overall responsibilities for the operations and the provision of the resources needed to ensure the required quality of laboratory operations.
- Lab manager has appointed deputies for the Lab manager, Technical manager, and Quality manager.
- Refer to Clinical Pathology Department Laboratory units organization chart. **F-NCI-CPD-QAU-QM002/02 (2-4)**

4.1 **Organization and mangement responsibility**

4.1.1 Organization:

Legal entity (4.1.1.2)

- The Clinical Pathology Department is part of National Cancer Institute. The labs gain their legal status as a part of a governmental academic institution; National Cancer Institute legally established as part of Cairo University (Decree 278/ 1981). It is legally identified to provide medical laboratory services, which meet the requirements of International Standard ISO 15189: 2012 and satisfy the needs of the client and the regulatory authorities.

Ethical Conduct (4.1.1.3)

Laboratory management has made arrangements in place to ensure the following:

- Laboratory Ethics will follow Egyptian regulation Egyptian Healthcare Accreditation organization, Standards for hospitals, Ethical code of laboratory medicine profession.
- Ethics are considered during all laboratory processes including:registration of patient data, collection of primary samples, analysis of samples; reporting of results, storage and retention of medical records, access to medical records, use of samples for examination purposes other than those requested, and avoiding situations that give rise to a conflict of interest.
- The responsibilities of key personnel in Clinical Pathology Department who have an involvement or influence on testing activities carried out by the laboratory units are defined in order to identify potential conflicts of interest.
- The laboratory units have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of deviations

from the quality system or from the procedures for performing tests and to initiate actions to prevent or minimize such deviations.

- Arrangements are applied to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work through:

1. **Undue Pressures:**

Policy

Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel. Management ensures that employees are never instructed or forced to alter or falsify data.

Details:

The following list provides some guidelines on how employees avoid conflict of interest situations.

Employees shall not:

 falsify records, prepare fraudulent reports, or make false claims

 seek or use privileged or confidential Lab information, or data from any customer, for any purpose beyond the scope of employment

 conduct non-laboratory business on laboratory time, or use lab facilities or equipment to conduct outside interests in business, unless prior approval has been obtained

 be employed by, or affiliated with, organizations whose services compete with laboratory products or services

 have employment that negatively affects or interferes with their performance of laboratory duties

 allow association, family, or friends to influence business decisions to their benefit - decisions must be made on a strictly business basis, always in the best interest of the laboratory

 make any decision that provides gains or benefits to the employee and/or others

 have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf .

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal .

2. **Customer Confidentiality**

Policy:

It is the policy of our laboratory to protect the confidential information and proprietary rights of our customer including the electronic storage and transmission of results.

Details and Procedures:

- **Employee Confidentiality Agreement**. All personel and staff members will sign a Confidentiality Agreement form, upon hirement, to ensure the committment to the privacy of patients data and Lab information. The signed agreement is maintained by the Laboratory Manager.

- All employees are required to utilize a username and password to access the Laboratory Information Management System (LIMS) which contains the proprietary and confidential information for all of CPD Laboratories customers.

- Test results are only released to the customer. Release to someone other than the customer requires the permission of the customer, except when the situation of pediatric patients, the parents are allowed to receive the reports, or in case of elderly patients with inability to judge.

- The release of test results to anyone other than the customer requires the permission of management. Laboratory reports are reviewed for accuracy prior to release.

3. **Operational Integrity**

Policy:

The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

Details and Procedures:

To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through check sample programs.

Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

4. **Respect to Patients Rights and Patient Safety**

- An Informed consent will be signed by the patient or his/her guardian before any invasive procedure and sampling of Bone marrow aspirates or biopsies, in which all the precautions, steps of the procedure and the possible complications will be clarified to the patient , for respecting patients' rights as well as for medicolegal issues

- Sample collection should not cause harm, for example infection or pain from the collection process and adverse events associated with bone marrow aspiration and

biopsy testing. Trained personnel are in place to prevent or manage any adverse events in the collection procedure.

- Proper identification of the patient or subject, and the Specimens are labeled with at least 2 unique identifiers, and all aliquot tubes are similarly identified
- Respect to the privacy of the patients during the sampling process, which is carried out in separated areas in the OP Sampling Area.
- The collection procedure is carried out using universal precautions to protect the patient and the healthcare worker, and should be performed with the least amount of patient discomfort possible by properly trained personnel.

Refer to :

Code of Ethics in Laboratory Services: NCI-CPD -QAU- QP014

Confidentiality Agreement form: F-NCI-CPD-QAU-QP014/1

Informed Consent form: F-NCI-CPD-QAU-QP014/2

Laboratory director (4.1.1.4)

The Head of Clinical Pathology Department, together with the board of the Department, is responsible for appointing a Laboratory Director for the Lab Units in all sections, including the BMT and HEM Lab Units. The Laboratory Directors are highly qualified and competent and are committed to the compliance to the ISO 15189:2012 Standards.

BMT and HEM Lab directors, according to their job descriptions, are responsible to:

a. Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.

b. Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.

c. Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users

d. Ensure the implementation of the quality policy

e. Implement a safe laboratory environment in compliance with good practice and applicable requirements

f. Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate

g. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results

h. Select and monitor laboratory suppliers

i. Select referral laboratories and monitor the quality of their service

j. Provide professional development programes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.

k. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services.

l. Monitor all work performed in the laboratory to determine that clinically relevant information is being generated.

m. Address any complaint, request or suggestion from staff and/or users of laboratory services.

n. Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; Contingency plans should be periodically tested.

o. Plan and direct research and development, where appropriate.

p. Communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements.

q. Ensuring that quality objectives and planning are established.
r. Defining responsibilities, authorities and interrelationships of all personnel.
s. Establishing communication processes.
t. Appointing a quality manager, however named.
u. Conducting management reviews.
v. Ensuring availability of adequate resources enable the proper conduct of preexamination, examination and post-examination activities.

4.1.2 Mangement responsibility

Quality Policy (4.1.2.3)

CPD Laboratory management has established a Quality Policy , in which it states its commitment to the requirements of the quality management system according to the ISO 15189:2012 Requirements. The Quality policy includes the commitment to good Laboratory Practice, to MOH regulations, to Health and Safety guidelines for staff, technicians and workers. The Lab Quality Policy states the intentions of the Lab Management to provide the highest technical lab services that will benefit NCI patients in Oncology field, with the well trained competent personnel and latest equipment, and ensures the continual improvement of quality of laboratory services.
The quality policy is announced, communicated and understood by the lab personnel, and reviewed regularly for suitability

Refer to
CPD Laboratories Quality Policy F-NCI-CPD-QAU-QP 007/01

Quality objectives and planning (4.1.2.4)

BMT and HEM Laboratory management have established their annual quality objectives, to meet the needs of the users and to maintain the continuous improvement of the laboratory services. The Quality objectives done are SMART, and comply with our Quality Policy

The management review that is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the QMS.

Refer to
Quality Policy and Objectives Procedure NCI-CPD-QAU- QP002

Responsibility ,authority and interrelationships (4.1.2.5)

Responsibilities, authorities and interrelationships are well documented and clarified in the organization charts and job descriptions. Each employee has been aware of his responsibilities and duties and has signed his /her job description.
Also, Authorizations are documented for each process.
The Lab Director has appointed a Technical Manager, and defined her responsibilities and duties and delegated some of her duties to the Technical Manager.

The roles and responsibilities of Technical Manager include

1. Overall responsibility for testing activities
2. Maintaining internal Quality checks
3. Participation in proficiency testing or inter laboratory quality checks
4. Review of requests
5. Subcontracting activities and correct assessment of the same
6. Identification of non conforming work and documenting the corrective action required
7. Correct recording and storage of test data for easy retrievability
8. Assessing training needs of personnel and arranging the same
9. Ensuring correct functioning of equipment and documentation related
10. Input on purchasing and storage of materials
11. Providing additional service to clients by way of interpretation and advice
12. Generating reports of tests and validation for affixing signature

In BMT and HEM labs, Deputies are appointed for:

- Lab Director
- Technical Manager
- Quality Manager

Communication (4.1.2.6)

Records for all Staff meetings are done, as well as, meetings with other Clinical departments to discuss their needs and any complaints. Communication within the Laboratory is established through emails, groups and scientific weekly meetings, quality mangement meetings, and Management Review meetings.
Verbal communication is well documented concerning patients results , critical values and rejected results
Refer to
Effective Communication Policy Code NCI-CPD-QAU-QP009

Quality manager (4.1.2.7)

Laboratory management has appointed the Quality manager, who has, delegated responsibility and authority that includes:

1. Assesses the facilities, procedures, practices, and training of personnel involved in the laboratory's activities, in regard to the QMS;
2. Reviews the quality plan annually and recommends any revisions needed to the Laboratory's Director/Manager;
3. Seeks advice from different departments and specialists and may require assistance from independent experts;
4. Establishes an internal audit program and informs the laboratory director/manager of audit outcomes;
5. Ensures that the quality management system is managed and maintained;
6. Establishes and monitors all processes and procedures for the quality management system;
7. Resolves nonconformities;
8. Ensures that action is taken in order to obtain continuous improvement of processes/activities;
9. Ensures all staff has up-to-date QMS training.
10. Ensures that processes needed for the quality management system are established, implemented, and maintained;
11. Reports to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
12. Ensures the promotion of awareness of users' needs and requirements throughout the laboratory organization.

Quality mangement system (4.2)
General requirements (4.2.1)

- Laboratory units have established, implemented and maintained quality management system (QMS) appropriate to the scope of its activities and in compliance with ISO 15189:2012
- QMS documentation structure is policies, system, programs, procedures, such as regulations, standards, other normative documents, test methods, as well as drawings,, specifications, instructions and manuals to the extent necessary to assure the quality of the test results.

- The system documentation is communicated to, understand by, available to and implemented by the appropriate personnel.
- This quality manual defines the overall objectives & procedures.
- The Laboratory has an established program that ensures regular monitoring, proper calibration and function of instruments, reagents and analytical systems. It also maintains documents on program of preventive maintenance and calibration, which, at a minimum, follows manufacturer's recommendations. Respective sections maintain the document for maintenance of equipment that belongs to their section.

Document control (4.3)

- The laboratory units have established and maintained procedures to control all documents that form part of its quality system (internally generated or from external sources).
- All documents issued to personnel in the laboratory as part of the QMS are reviewed for their adequacy and approved for use by supervisor prior to issue. A master list identifying the current revision status and distribution of documents in the quality system is established and be readily available to preclude the use of invalid and/or obsolete documents.
- Records are established and maintained to provide evidence of conformity to requirements and effective operation of the quality management system. Records remain legible, readily identifiable and easily retrievable. Controls are applied for identification, storage, protection, retrieval, retention time and disposition of quality and technical records.
- Changes to documents by hand are not permitted.
  Refer to:
  Documents, Data and Records Control Procedure (NCI- CPD-QAU-QP-001).

Service agreements (4.4)

Establishment of service agreements (4.4.1)

The laboratory has a documented procedure for the establishment and review of agreements for providing medical laboratory services.

The contractual arrangement between the laboratory and its users is defined by the laboratory request form that is completed either manually through Lab Request form or electronically (under final installment and trial)

Each request form (together with its relevant primary samples) is checked for conformity with the laboratory's labelling requirements which are made available to users via the laboratory's internet website and Lab Service manual. If the form or samples do not meet

these requirements then the request may be rejected, the user notified of this and a repeat sample requested.
ed.
Refer to

Service Agreements Policy NCI-CPD-QAU- QP0011

Review of service agreements (4.4.2)
The procedure for review of service agreements has been established as part of ISO 15189 : 2012 requirements.
Formal contract reviews occur at least annually to ensure that user satisfaction is being maintained. The review also ensures that the requirements of both parties are adequately defined, documented and understood.

Refer to:
Review of Service Agreement Procedure NCI-CPD-QAU-QP012

Examination by referral laboratories (4.5) N/A
The laboratory is a reference lab for all tests in the field of Oncology , and the presence of many scientific consultants who can add to the quality of laboratory services, with their expertise.
Tests within the scope of accreditation are not sent to analysis to referral laboratories.

External services and supplies (4.6)

- The laboratory has established and implemented a policy and procedure for the selection and purchasing of services and supplies it uses that affect the quality of the tests, and evaluation of suppliers. It is applied for reception and storage of reagents and laboratory consumable materials relevant for the tests.
- The technical supervisor ensures that purchased supplies and reagents and consumable materials that affect the quality of tests and/ or test, are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements, defined in the methods for the tests and/ or tests concerned. Records of actions taken to check this compliance are maintained.
- Purchasing documents for items affecting the quality of laboratory output contains data describing the services and supplies ordered. Purchasing documents are reviewed and approved for technical content prior to release.
- The laboratory evaluates suppliers of critical consumables, supplies and services which affect the quality of testing and test and maintains records of these evaluations and list those approved suppliers.

- The laboratory purchasing process are compatible with the general purchasing process of National Cancer Institute
- A list of approved suppliers of equipment, reagents and consumables is kept within the purchasing Department.
- While a list of the Blacklisted Suppliers are kept with the Laboratory Management
- .The performance of these suppliers is monitored as part of supplier reviews with the details of this monitoring recorded within the form of Evaluation of supplier تقييم أداء مورد
- Refer to

Purchasing procedure NCI-CPD-QAU-QP013
Reagents and Consumables Management Procedure NCI-CPD-QAU- TP 008
Reagents /Consumables Record F-NCI-CPD-HEM-QAU-TP008/01
Evaluation of supplier تقييم أداء مورد نموذج F-NCI-CPD-QAU-QP 13/02

Advisory services (4.7)

The laboratory units have efffective arrangements for advisory services that include:

- Interpretation of results and recommendation for further investigations and frequency of follow up are included in the Report forms under comments
- Recommendation for further investigations and frequency of follow up
- Creating awareness among healthcare team concerning availability of new test sand techniques or interpretation of results.
- Lab to lab service as regards type of sample required and storage conditions
- Staff meeting for sharing knowledge
- The advisory services is provided through report comments, seminar meetings, laboratory units website
- Regular meetings of laboratory and clinical staff occurs routinely in the regular NCI scientific meeting every Monday morning.
- The staff of the lab (with relevant speciality) participate in the weekly meetings of other departments for discussion of individual cases or other issues related to patient's laboratory services
- Announcement of Seminars and new tests is done by memorandum sent to other departments as well as through the NCI website: www.nci.cu.edu.eg

Refer to

Post-Examination processes of BMT Lab:
Reporting and Release of Results NCI-CPD-BMT-QAU-TP010

Post Examination processes of HEM Lab :
Reporting and Release of Results in HEM Lab NCI-CPD-HEM-QAU-TP005

Effective Communication Policy NCI-CPD-QAU-QP009

Resolution of complaints (4.8)

- The laboratory has established and maintained a policy and procedure for the resolution of complaints received from clients or other parties**.**
- Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.
- The record of complaints and of investigations and the corrective actions taken by laboratory is maintained in a register
- Refer to

Customer Complaint and Client Service Procedure : NCI-CPD-QAU-QP-016
Customer Complaint form نموذج شكوى-اقتراح F-NCI-CPD-QAU-QP-016/01
Customer Complaint follow up نموذج متابعة شكوى عميل F-NCI-CPD-QAU-QP-016/02
Customer complaint register سجل التغذية الراجعة للمريض F-NCI-CPD-QAU-QP-016/03

Identification And Control Of Nonconformities (4.9)

- The laboratory has established and maintained a policy and procedure implemented when any aspect of its test work, or the results of this work, does not conform to its own procedures or the agreed requirements of the client.
- The policy and procedures ensure that:
  - The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports, as necessary), for authorizing the resumption of work are defined.
  - An incident report is filled by the person responsible to detect the nonconformity and analysis of the causes of the problem is done with a suggested corrective action.
  - An evaluation of the medical significance of the nonconforming work is made.
  - Corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work.
  - Where necessary, the client is notified and work is recalled.
  - Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures shall be promptly followed.
  - Refer to

Control of Non Conformity Procedure NCI –CPD-QAU-QP-004
Incident Report F-NCI-CPD-QAU-QP004/03

Corrective action (4.10)

- The laboratory has established and maintained a policy and procedure and designates appropriate authorities for implementing corrective action when nonconforming work

or departures from the policies and procedures in the QMS or technical operations have been identified.

- Where corrective action is needed, the laboratory identifies potential corrective actions. It selects and implements the action(s) most likely to eliminate the problem and to prevent recurrence
- Corrective actions are appropriate to the magnitude and the risk of the problem.
- The laboratory documents and implements any required changes resulting from corrective action investigations.
- The laboratory monitors the results to ensure that the corrective actions taken is effective.
- Where the identification of nonconformance's or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with ISO 15189: 2012 International Standard, the laboratory ensures that the appropriate areas of activity are audited in accordance with Internal audits procedure.
- Refer to

Corrective and Preventive Action Procedure NCI-CPD-QAU-QP 005

Preventive action (4.11)

- The laboratory has established and maintained a preventive action procedure that includes the initiation of such actions and the applications of controls to ensure that they are effective..
- A preventive action is established when there is a need for improvement and potential source of nonconformances, either technical or concerning the QMS are identified.
- Action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformance's and to take advantage of the opportunities for improvement.
- Refer to

Corrective and Preventive Action Procedure NCI-CPD-QAU-QP 005

Continual imrovement (4.12)

The laboratory continually improves the effectiveness of its quality management system through the use of quality policy, quality objectives, audit results, performance measurement, corrective and and preventive actions and management review

4.12.1

Technical Lab Manager systematically reviews all operational procedures annually in order to identify any potential sources of non-conformances or for any opportunities for improvement. Action plans developed for improvement are documented and implemented

4.12.2

A focused audit is continued on the proposed changes that were done as a result of review of procedures. An evaluation is done for the effectiveness of the changes made.

4.12.3

The results of audit are submitted to Technical Manager for review. It is discussed with Laboratory Director and Quality Manager about the needed changes that are documented and implemented in the Quality Management System

4.12.4

Laboratory Management implements quality indicators like internal QC, duplicate testing, participation in EQAS for systematically monitoring and evaluating the Laboratory's contribution to patients care. In the Continual improvement process, the Lab management addresses it.

4.12.5

Laboratory Management continuously encourages and ensures that the lab personnel undergo training programs and attend C.M.E. for their continual improvement in their technical expertise.

Refer to :

- Quality Policy and Objectives NCI-CPD-QAU-QP-002
- Quality Indicators Procedure NCI-CPD-QAU-QP-017
- Quality Indicators List F-NCI-CPD-QAU-QP-017/01

Control of records (4.13)

- The laboratory has established a procedure for identification, collection, indexing, access, filling, storage, maintenance and disposal of quality and technical records. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.
- All records are legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
- Retention times of records are established and are held secure and in confidence according to the procedure in **List of Records form F-NCI-CPD-QAU-QP-001-6**
- The laboratory has established and maintained procedure to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.
- The laboratory retains records of original observations; derived data and sufficient information to establish an audit trail, test records, staff records and a copy of each test certificate issued, for a defined period. The records for test contain sufficient information to facilitate the identification of factors affection the uncertainty and to enable test to be repeated under conditions as close as possible to the original.

- The records include the identity of personnel responsible for performance of each test and checking of results. Observation, data and calculations are recorded at the time they are made and are identifiable to the specific task.
- When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted and the correct value entered alongside. All such alterations to records are signed or initialed by the person making the correction, In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

- Refer to
  Documents, Data and Records Control NCI –CPD-QAU-QP-001

Evaluation and audits (4.14)

Periodic review of requests,and suitability of procedures and requirements (4.14.2)
Laboratory Director and Technical Manager have reviewed the list of tests provided by the laboratory to ensure that they are clinically appropriate for the requests received, and this is done annually.
A new request form for CBC and Coagulation profile has been provided to the clinicians in the Outpatient clinic and wards and it is to be implemented electronically .
In BMT lab, a new request has been prepared for New cases, and one for Minimal Residual Disease tests (MRD), and they are implemented. Request forms are finalized according to ISO 15189:2012 requirements, as well as Report forms.
The introduction of new devices for sampling and sample processing was done by the lab management in HEM section, as well as bar-coding system for the accurate identification of the patients and their samples

Assesment of user feedback (4.14.3)
The Laboratory has a documented procedure for assessment of Customer satisfaction, the survey is carried out annually in the Sampling area for clinicians and patients. The samples are analysed and causes of unsatisfaction are examined and prioritised for improvement plans.
Direct interaction with the different clinicans occurs during the staff meetings and weekly Scientific conference of NCI, and feeedback is collected by Laboratory management. Complaints and documented problems are recorded and actions taken. Customer complaints are discussed during the Management review meetings for follow of resolution of complaints.
Refer to
Customer Satisfaction Policy NCI-CPD-QAU-QP-010
Patient's Satisfaction Survey F-NCI-CPD-QAU-QP-010-01
Doctor's Satisfaction Survey for Lab Services F-NCI-CPD-QAU-QP-010-02

Staff suggestions (4.14.4)

Records of Staff suggestions and actions taken by the management are documented and maintained. Lab Management Meetings are documented and include Staff suggestion for improvement.

Staff suggestions for improvement are discussed during the Management review meetings.

Staff Suggestions form F-NCI-CPD-QAU-QM 01/02

Internal audit (4.14.5)

a) **Frequency, Content and Responsibility for Internal Audits**

The internal audit program described in Internal Audit Procedure that addresses all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Such audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

The cycle for internal auditing shall be completed once per year.

b) Corrective Action for Internal Audits

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify personnel or customers if investigations show that the laboratory results may have been affected, as described in Corrective and Preventive Procedure NCI-CPD-QAU-QP 005

c) Documentation of Audits

The area of activity audited, the audit findings and corrective actions that arise from them is recorded as described in Internal Audit Procedure .

d) Verification of Internal Corrective Action

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken prior to the corrective action being closed

Refer to

Internal Audit Procedure NCI-CPD-QAU-QP-003

Risk management (4.14.6)

The laboratory has established a documented procedure for Risk Management, which describes the ways to evaluate and asses the risks or potential failures that might affect patient safety and affect the quality of laboratory services.

The potential risks are evaluated according to probability or likelihood and severity .

Refer to

Risk Management Procedure NCI-CPD-QAU- QP018
Risk register-1-probability and severity for BMT & HEM labs F-NCI-CPD-QAU-QP018/01
Risk assessment report for BMT and HEM labs F-NCI-CPD-QAU-QP018/02
Medical Laboratories Safety Checklist F-NCI-CPD-QAU-QP018/03

Quality indicators (QI) (4.14.7)

- Quality indicators are regularly monitored and the results are used as indicators for the performance of the QMS and the Laboratory services. Quality Indicators are discussed regularly in the Management Review meetings.
- The Lab management has chosen a set of 19 QI to assess the pre-examination, examination and post examination processes, as well as non -analytic processes.
- Refer to
  - **Quality Indicators Procedure NCI-CPD-QAU-QP-017**
  - **Quality Indicators List F-NCI-CPD-QAU-QP-017/01**

Reviews by external organizations (4.14.8)

Ongoing evaluation and improvement processes are essential to ensure that the service provided by the CPD Labs, meets the needs and requirements of its users. Recording, analysis and interpretation of the evaluation data is an important element of the management process and as such forms part of discipline specific management reviews.

- External quality assessment (Proficiency testing by participating in CAP Survey in BMT Lab, and in RIQAS- EQAS in HEM Lab)
- Reports from external bodies as EGAC
- Simulation Audits and Gap Analysis by External Company for Quality and Accreditation

Results of evaluation and improvement are made available to all staff through staff and other

Lab group meetings. The analysis and recording of evaluation and improvement processes form a standard agenda item at CPD Lab Annual Management Reviews.
Each discipline as BMT and HEM LAB have participated in approved External Quality Assessment Schemes as mentioned, appropriate to the examinations and interpretations provided.
Records of performance in these schemes are maintained by the laboratory management teams, reviewed and communicated to staff as a regular agenda item at departmental staff meetings. Decisions taken by disciplines in relation to their performance are recorded, acted on and monitored

4.15 Management review

The management team within each discipline conducts an annual review, the content of which is detailed in the Procedure. Records are kept, key objectives for subsequent years are defined and plans are formulated for their implementation. The input to management review includes information from the results of evaluations including:

a) The periodic review of requests, and suitability of procedures and sample requirements
b) Assessment of user feedback
c) Staff suggestions
d) Internal audits
e) Risk management
f) Use of quality indicators
g) Reviews by external organizations
h) Results of participation in inter-laboratory comparison programs
i) Monitoring and resolution of complaints
j) Performance of suppliers
k) Identification and control of nonconformities
l) Results of continual improvements including current state of corrective actions and preventive actions
m) Follow up actions from previous management reviews
n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system
o) Recommendations for improvement, including technical requirements

The review of activities (4.15.3) must analyze the information about causes of nonconformities, trends and patterns that may indicate process problems. This review shall

include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
The quality and appropriateness of the laboratory's contribution to patient care is evaluated.

The output from the management review (4.15.4) is incorporated into a record that documents any decisions made and actions taken during management review related to:
a) Improvement of the effectiveness of the quality management system and its processes
b) Improvement of services to users
c) Resource needs
The interval between management reviews is 12 months. Shorter intervals were adopted when the quality management system was being established and after the external assessments.
Findings and actions arising from management reviews are recorded and reported to laboratory staff. Laboratory management are committed to ensure that actions arising from management review are completed within a defined timeframe.
Refer to:

Management review Procedure (NCI-CPD-QAU- QP006)

5 Technical reqirements

5.1 Personnel :

Professional Leadership:

The CPD is lead professionally by the Head of Department, and each Lab is directed by the Laboratory Director, who is qualified to manage and lead the lab activities .
The Lab Director assigns a Technical Lab Manager , and a Quality manager, and must assign Deputies for the Key personel positions.
The Labs have a team of qualified consultants and staff members who have received training and education at the National Cancer Institute and can perform efficiently to meet the customers' requirements.
The Laboratories of BMT and HEM units have procedures for:

- Personnel Management Procedure
- Staff Training and Competency Assessment procedure
- Performance Appraisal procedure

Staffing

Staff records and evidence of appropriate professional qualifications are held securely by the Head of CPD Department. These records are also held by the NCI Human Resources department.

The CPD Lab Management Team ensures that there are appropriate numbers of staff, with the required education and training to meet the demands of the service and the appropriate

National legislation/requirements. Registration of staff is in accordance with current national legislation and regulations.

Job Descriptions (5.1.3)

All staff job descriptions are produced using the format for Job descriptions.

Job descriptions are discussed annually at the Management meetings and are kept in individual personal records.

Copies are held by the Quality Management Unit at NCI, and HR department, as well each individual member of staff.

Personnel introduction to the organizational environment (5.1.4)

New staff are invited to attend an Induction training which is held at each lab. Copies of Induction records are held by individual staff members and in departmental staff records held by the Lab Directors

Refer to :

Training and Competency Assessment Procedure NCI-CPD-QAU-TP002

Training (5.1.5)

Clinical Pathology Department is committed to the mission of NCI , being a training and education research institute in Oncology. The training of the staff members and technicians is a vital part in the lab activities.

The HEM and BMT Laboratories have training and education programs in accordance with the requirements of lab customers.

Training covers all aspects of work in the laboratories that each member of staff is required to carry out (examination procedures) or participate in including the Quality Management Systems, the LDM system, Ethics, and Health and Safety, and confidentiality of patient information.

Staff have access to education and training which meets their needs and position within the organization. Training plans are identified at annual Management review meetings, and may be part of the Continual Improvement plans , or Quality objectives.

Training records are held in training folders by each lab for all staff. These folders contain details of initial training and competency assessments which involve a direct observation of the work process and checklist to assess the staff' knowledge on the process, and interpretation (5.1.6).

Refer to :

Training and Competency Assessment Procedure NCI-CPD-QAU-TP002

Training Programs for Assistant Lecturers

Training Programs for Technicians

Reviews of Staff Performance (5.1.7)

The labs have a documented procedure and a format for the performance appraisal of staff members and technicians

All staff members have an annual Performance appraisal that includes:

☐ Job description of the staff member.
☐ Personal objectives of the staff member.
☐ Training and development needs of the staff member.
☐ Staff' ContinualProfessional Development to ensure that it is appropriate

Records of Annual Performance appraisal are maintained in individual staff records by Head of Department.

Refer to :

Performance appraisal for Clinical Pathology Staff NCI-CPD-QAU-TP003
Performance Appraisal of Resident And Assistant Lecturer Procedure NCI-CPD-QAU-TP004

Continuing education and professional development (5.1.8)

Continual Professional Development (CPD) is undertaken and recorded by the staff that have access to attend Lab Management meetings and attend internal and external courses. The CPD has designated training representatives in each Lab , who together with the Quality Manager constitute the Training and Education Committee.

Personnel files and staff records (5.1.9)

Each member of staff has a local personal file and staff records are maintained in accordance with NCI Policy. Staff records are kept for each member of staff and held securely, to maintain confidentiality, by Head of Department and are continuously maintained and updated to include:

☐ Personal and contact details
☐ Educational and professional qualifications(5.1.9a)
☐ Copy of certification or license(5.1.9b)
☐Previous work experience (5.1.9c)
☐ Job description(5.1.9d)
☐ Induction and Orientation record(5.1.9e)
☐ Training record(5.1.9f)
☐ Competency assessments(5.1.9g)
☐ Records of continuing education and achievements(5.1.9h)
☐ Reviews of staff performance(5.1.9i)
☐ Accident record(5.1.9j)
☐Immunization status (5.1.9k)
☐Confidentiality agreement(4.1.1.3e)

Accommodation and Environmental Conditions (5.2)

Laboratory and office facilities (5.2.1)

The laboratory provides accommodation and conditions for staff that are appropriate to the correct performance of their respective duties in accordance with MOH Regulations and Infection Control Guidelines. Offices are locked when not in use. To ensure the quality of results of examinations laboratory areas containing equipment and reagents that may be affected by environmental factors such as temperature, dust, humidity etc. are continually monitored. Annual health and safety audits are undertaken to ensure that safety facilities and devices are available.

Facilities for Storage (5.2.3)

There are areas of storage located throughout the CPD. Separate, external storage containers are provided for the storage of flammables, in accordance with health and safety requirements. There is temperature controlled storage space for reagents, samples and other material as required which are stored in a manner that prevents cross contamination and separates expired and waste material.

Facilities for Staff (5.2.4)

There are adequate staff facilities within the hospital including:

a) Sufficient toilet accommodation.
b) Shower facilities where required.
c) A rest area
d) Basic catering facilities and access to a supply of drinking water.
e) A changing area and secure storage for personal effects.
f) Safe and secure working arrangements.
g) Staff Cafeteria
h) ATM.

Facilities for patient sample collection facilities (5.2.5)

There are patient sample collection facilities for general use in the Outpatients Phlebotomy area at NCI, in the Out patients Clinics. These facilities have separated waiting and collection areas with use of curtained cubicles including one appropriate for disabled access.

Facilities maintenance and environmental conditions (5.2.6)

The laboratory is designed to provide effective separation between non-compatible activities e.g. the use of separate areas for specialized testing e.g. PCR. Where appropriate, factors that may affect the quality of result or working conditions are monitored constantly via use of thermometers.

It is the NCI policy to provide and maintain a safe and healthy working

environment for all its employees and visitors by meeting the Health and Safety standards. The term 'visitors' includes those delivering goods, contractors, company representatives, other visiting professional groups or patients delivering samples.

Refer to :

- **Laboratory Safety manual NCI-CPD -QAU-LSM-01**
- **Accommodation and Environmental Conditions Management Policy Code: NCI-CPD-QAU-TP005**
- **Medical Laboratories Safety Checklist F-NCI-CPD-QAU-QP018/03**

Laboratory Equipment, reagents and consumables (5.3)

The CPD has a documented procedure for the selection, purchasing and management of equipment. The laboratory is furnished with all items of test equipment required for the correct performance of the testing (including preparation of samples, processing and analysis).

The Laboratory identifies new and replacement equipment ensuring that quality and capacity is addressed and meets the needs of its users (5.3.1.1). The CPD complies with national guidelines and the NCI policy for purchase, installation, training and safe disposal of all equipment.

It also complies with Cairo University policies for standing orders, tendering and contract procedures and standing financial instructions that include compliance with legislation for:

☐ Fair competitive tendering.
☐ Value for money.
☐ Suitability and ease of use.

The process for the management of new equipment is described in the Equipment Management Policy **(Equipments Management Procedure for HEM NCI-CPD-QAU-TP 006), and (Equipments Management Procedure for BMT NCI-CPD-QAU -TP 007)** is in accordance with the NCI policy and includes:

- Assessment of the justification of need.
- Selection.
- Acceptance (includes using Design Qualification, Installation Qualification, Operational
- Qualification and Performance Qualification (5.3.1.2)
- Training (5.3.1.3)
- Preventive maintenance, service and repair
- Calibration and monitoring of instruments, reagents and analytical systems
- Decontamination

- Recording of instrument failure and subsequent corrective actions
- Planned replacement taking into consideration energy usage and care of the environment.
- Disposal of equipment.
- Adverse incident and vigilance reporting. (5.3.1.6)

There is an inventory of equipment held on the LAB software that includes:

- Identity of equipment (5.3.1.7a)
- Manufacturer, model and serial number (5.3.1.7b)
- Contact information for supplier or manufacturer (5.3.1.7c)
- Date of receipt and date entered into service (5.3.1.7d)
- Location (5.3.1.7e)
- Condition when received (5.3.1.7f)

▪ In each department full equipment records are held containing manufacturer's instructions (5.3.1.7g), equipment maintenance records (5.3.1.7i), validation documentation (5.3.1.7h), yearly maintenance, acceptance for use records (5.3.1.7j) and details of damage or repair (5.3.1.7k).

▪ Laboratory staff will only be permitted to use equipment unsupervised when the appropriate senior member of staff has established that they are competent and confident to do so. This will be documented accordingly in the individual's training record.

▪ Electrical safety checks are carried out regularly and all equipment is marked, identifying the last inspection date and when the next inspection is due. Where appropriate, equipment will be regularly maintained by hospital engineers or through a maintenance contract with external engineers.

▪ When it is necessary for equipment to be commissioned and/or calibrated prior to use, this is carried out by a relevant body ensuring metrological traceability (certificates of traceability issued). Manufacturer's operating manuals and maintenance manuals are held in the relevant section of the laboratory and are used when creating procedures for the equipment.

▪ Use of precision pipettes, automated and semi-automated analyzers, centrifuges, balances, fridges, freezers, incubators and timers are an essential part of CPD lab procedures used to produce accurate test results. These pieces of equipment therefore must be regularly calibrated to ensure traceability of the results which they provide.

▪ When equipment goes outside the direct control of the laboratory, the laboratory ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

▪ The laboratory established a procedure to carry out intermediate checks needed to maintain confidence in the calibration status of the equipment.

- Where calibrations give rise to a set of correction factors, the laboratory establishes and maintains procedures to ensure that copies (e.g. in computer software) are correctly updated.
- Test and calibration equipment, including both hardware & software are safeguarded from adjustments, which would invalidate the calibration result.

Refer to

HEM LAB Equipments Management Procedure NCI-CPD-QAU-TP 006

BMT LAB Equipments Management Procedure NCI-CPD-QAU -TP 007

Management of reagents, calibration and control materials (5.3.2)

The CPD LAB ensures the funding and availability of adequate and suitable materials required to provide a quality service for users. The Management of Reagents, Calibration and Controls and Consumables procedure includes
(Reagents and Consumables Management Policy NCI-CPD-QAU-TP008):

a) Reception and storage (5.3.2.2)
b) Acceptance testing (5.3.2.3)
c) Inventory management (5.3.2.4)
d) Instructions for use (5.3.2.5)
e) Adverse incident reporting (5.3.2.6)

Reagents and materials are labeled, when appropriate, with date of receipt, lot number, first use and expiry date. Records of the management of reagents are kept within individual labs either as a manual record or embedded within the analyzer information system and include:

☐ Identity of the reagent or consumable(5.3.2.7a)
☐ Manufacturer's name and batch code or lot number(5.3.2.7b)
☐ Contact information for the supplier or the manufacturer(5.3.2.7c)
☐ Date of receipt, expiry date, date ofentering into service and, where applicable, the date the material was taken out of service (5.3.2.7d)
☐ Condition when received (accepted or damaged)(5.3.2.7e)
☐ Manufacturer's instructions(5.3.2.7f)
☐ Records that confirmed the reagent's orconsumable's initial acceptance for use (5.3.2.7g)
☐ Performance records that confirm the reagent's or consumable's initial acceptance for use (5.3.2.7h)

Refer to:

Reagents and Consumables Management Policy NCI-CPD-QAU-TP008
Reagents /Consumables Management form F-NCI-CPD-QAU-TP008/01

Pre-Examination Processes (5.4)

5.4.4 Primary sample collection and handling

5.4.4.1 l
The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations, (**Laboratory Sample Collection Manual LSCM-01**) which is available to all users and customers in the Lab and at NCI, and on the NCI website. The HEM and BMT Labs have implemented the Informed consent for the invasive procedures as Bone marrow Aspirate and Trephine biopsy. The details and possible complications of the procedure are explained to the patient and the informed consent must be signed by the patient and the doctor.

In case of routine laboratory testing as in CBC and Coagulation profile tests, the Request is considered a consent to carry out the test.

Information for patients and users (5.4.2)
Information for the users of the service is found in **Laboratory Service Manual and Laboratory Sample Collection Manual** which are located on the NCI internet website and in the Outpatient Clinics area. These Manuals provide information on the location and opening times of the department, instructions for completing request forms and patient preparation, submitting samples and the test repertoire. Contact information of Laboratory at NCI, and the availability of clinical advice and interpretation is also included. Each User Manual is reviewed and updated regularly.

Request form information (5.4.3)
The request forms are designed to provide all relevant information required to provide a safe and meaningful report including clinical advice and to satisfy minimum internal audit requirements.
In Hematology Lab, a combined Request form for CBC and Coagulation profile has been implemented fulfilling the requirements of the standard.
In BMT Lab, a combined Request form for the Blood Tests required for a New Case including Immunophenotyping, Fusion Genes, HLA typing.
In case of Minimal Residual disease (MRD) detection, a separate Request form has been implemented
Request forms provide space for:

- Sufficient information to allow correct identification of the patient (5.4.3a)
- Identification of the location and of the requesting individual (5.4.3b)
- Type of specimen and anatomical site of origin if relevant. (5.4.3c)
- Investigation required (5.4.3d)
- Relevant clinical information (5.4.3e)
- Date and time of specimen collection (5.4.3.f)
- Date and time of receipt of sample by the laboratory (5.4.3g)

Samples that do not meet the minimum requirements described in the Laboratory Sample Collection Manual, according to "Acceptance and Rejection Criteria of Blood Samples" (Laboratory Sample Collection Manual LSCM-01), are dealt with in the manner described in this policy. This policy is communicated to all personnel and is supported by departmental SOPs.
Verbal requests for examinations are not Applicable at our Lab.

Primary sample collection and handling (5.4.4)
The procedures for the collection and handling of samples are documented in the (Laboratory Sample Collection Manual LSCM-01), and are available on the NCI website and Laboratory computers in PDF to all users.
Specimen Transportation (5.4.5)
Information and advice is available for all users of the service in the Laboratory Sample Collection Manual LSCM-01), and on the NCI website. This information includes how samples should be transported to the laboratory, including labeling and packaging and also gives time frames to ensure that samples arrive in optimum condition for analysis at the correct temperature range and in a manner suitable to ensure the integrity and safety of carrier, general public and receiving laboratory
Refer to

Operating Procedure of Sampling Outpatient Clinics NCI-CPD--QAU-TP009

Transport of Hospital Samples

The Laboratory receives samples that are transported in a leak-proof, well-sealed ice box via the Lab porter from the following areas
of the hospital:

1. Sampling Outpatient Clinic for Adults (Phlebotomy area)
2. Sampling Outpatient Clinic for Pediatrics

And by the Medical Secretaries for Inpatients from :

1. Surgical Inpatient Wards
2. Medical Oncology Inpatient Wards including Chemotherapy Day Care Unit.

3. Pediatric Oncology Inpatient Wards

- In BMT Lab, samples may be delivered at the lab by the external patients themselves or the samples may be collected at the Lab in HLA typing cases. Also, in case of Fusion genes, requested from other hospitals, the samples maybe delivered by the Hospital Lab representatives

- **Specimen Reception (5.4.6)**

All samples are received into the Lab Sample Reception (LSR) area at the Main lab (samples for Hematology Lab including CBC and Coagulation tests).
Bone marrow and Peripheral Blood Samples that are collected from the Bone marrow sampling Room , are directed to the BMT Lab.

The Sample Acceptance and Rejection Criteria which are documented in (Laboratory Sample Collection Manual LSCM-01) **are** supported by Lab procedures for specimen reception of all samples Handling and Storage of Clinical Samples Procedure **NCI-CPD-BMT-QAU- TP 011)**. Master copies are held in the QMS with hardcopies available at the point of use and include:

☐ Linking the request form to the sample (including secondary samples) to ensure traceability (5.4.6a)
☐ Using pre-defined acceptance criteria (5.4.6b) to compare each sample with and ensure they meet the requirements (5.4.6e)
☐ Ensuring that if a sample does not meet sample rejection criteria, a report is issued to indicate the reason for non-testing (5.4.6c)
☐ Data entry onto the LIMS, recording the date and time of receipt(5.4.6d)
☐ Instructions on processing samples marked as urgent(5.4.6f)

Reasons to reject specimens for Lab Unit tests are:

- Whole blood specimen:

A. Improperly labeled or unlabeled specimen.
B. Wrong request (incompatible with patient ID on sample, test required or sample collected).
C. Clotted specimen.
D. Failure to meet volume criteria.
E. Leaking tube.
F. Delay in transport beyond the retention time for each test.
G. Collection of specimen in wrong tube.

- BMA specimen:

A. Improperly labeled or unlabeled specimen.
B. Wrong request (incompatible with patient ID on sample, test required or sample collected).

C. Clotted or markedly diluted samples for IPT or Molecular genetics. A repetition may be requested for IPT only if no cells are detected in the sample.

Pre-examination handling, preparation and storage (5.4.7)

The laboratory ensures that all samples are stored securely in the laboratory using controlled access and temperature controlled storage areas to prevent deterioration, with methods employed to easily retrieve a sample if required. Sample retention time is detailed in the documented procedure, for use in additional or repeat testing.

Refer to :

Laboratory Sample Collection Manual LSCM-01

Reporting and Release of Results Procedure in HEM LAB: NCI-CPD-HEM-QAU-TP005

Handling, Storage, Retention And Disposal Of Clinical Samples in BMT LAB : NCI-CPD-BMT-QAU- TP 011

Examination Processes (5.5)

Selection,verification and validation of examination procedures (5.5.1)

Examination procedures within the HEM and BMT Labs are selected to ensure that suitable investigations are available for clinicians to both diagnose and monitor patients and meet the requirements of the Medical Guidelines that are followed by the Clinical Departments at NCI and ISO 15189 : 2012 Standard.

The Examination procedures are following the Standard Methods, and are verified prior to introduction to use and involve design qualification, installation qualification, operational qualification and performance qualification.

The laboratories have documented the procedure used for the Verification and have recorded the results obtained. The Laboratory Director with the Technical Manager and staff members with the appropriate authority, reviewed the verification results and recorded the review. **(5.5.1.2)**

Copies of all procedures are kept in the QMS , issued as hard copies and are available in the relevant areas of the Clinical Pathology Department Labs.

Biological reference intervals or clinical decision values (5.5.2)

In HEM Laboratory , the biological reference intervals have been defined in CBC according to age and sex, and Coagulation profile tests.

Refer to :

Examination Methods (below)

Documentation of examination procedures (5.5.3)

Procedures for all examinations carried out in the HEM and BMT Labs include:

a) Purpose of the examination
b) Principle and method of the procedure used for examinations
c) Performance characteristics
d) Type of sample
e) Patient preparation
f) Type of container and additives
g) Required equipment and reagents
h) Environmental and safety controls
i) Calibration procedures
j) Procedural steps
k) Quality control
l) Interferences
m) Calculation of results
n) Measurement of uncertainty or measured quantity values
o) Biological reference intervals and clinical decision values
p) Reportable interval of examination results
q) Determining quantitative results outside the measurement interval
r) Critical values
s) Laboratory clinical interpretation
t) Sources of variation
u) References
v) -ISO 15189:2012 Standards

Methods are assessed to identify areas that have the potential to introduce variation. Control measures are applied as appropriate to reduce any uncertainty with regard to consistency and accuracy of results. Refer to the Determination of Uncertainty inside the Examination Procedures.

Refer to :

Examination Procedures for HEM and BMT LABS:

No.	Hematology Examination Procedures	Code
1.	**Complete Blood Count Procedure**	**NCI-CPD-HEM-QAU TP001**
2.	**Coagulation Profile Procedure**	**NCI-CPD-HEM-QAU TP002**
3.	**Verification Methods of CBC and Coagulation Profile**	**NCI-CPD-HEM-QAU TP003**

No.	BMT Examination Procedures	Code
1.	**Measurement of DNA index Procedure**	**NCI-CPD-BMT-QAU-TP001**

2.	Enumeration of CD34 positive progenitor stem cells	NCI-CPD-BMT-QAU-TP002
3.	Immunophenotyping of Acute and Chronic Leukemia Procedure	NCI-CPD-BMT-QAU-TP003
4.	Molecular HLA-A,B and DRB1 Typing (Reverse Sequence specific oligonucleotide probe) using strip assay	NCI-CPD-BMT-QAU-TP004
5.	Molecular Class I & II typing (Luminex technology	NCI-CPD-BMT-QAU-TP005
6.	Detection of JAK2V617F mutation	NCI-CPD-BMT-QAU-TP006
7.	Fusion Gene Transcripts Detection	NCI-CPD-BMT-QAU-TP007
8.	Detection of Nucleophosmin mutation	NCI-CPD-BMT-QAU-TP0018
9.	SOP Verification Immunogenetics	NCI-CPD-BMT-QAU-TP0019
10.	SOP Verification Fusion genes transcript detection	NCI-CPD-BMT-QAU-TP0020
11.	SOP Verification JAK2V617F mutation	NCI-CPD-BMT-QAU-TP0021
12.	SOP Verification Flow Cytometry	NCI-CPD-BMT-QAU-TP0022

Ensuring Quality of Examination Results (5.6)

There are procedures in place in each Lab for Internal Quality Control (IQC) to ensure the quality of all laboratory examinations and are reviewed daily to ensure that examination results are valid before release. Records are maintained of the date, source and storage requirements of IQC material.

Procedures for External Quality Assessment (EQA) are in place wherever schemes are available for assays and are suitable (i.e.: reflect a normal case and can be tested using standard procedures for the assays).

HEM Lab has participated in RIQAS program for CBC and Coagulation on monthly basis .
BMT Lab Has participated in CAP Survey program for Flow cytometry, HLA typing and Immunogenetics, and Fusion Genes, according to the scheme, vials are sent biannually.
By undertaking EQA, the performance of HEM and BMT Labs against set marked criteria is reviewed and presented to show how the CPD compares to other hospitals using the same technology and against other suppliers.

Results of IQC and EQA are made available to concerned staff and are fixed agenda items at annual Management review meetings.
Discrepancies are recorded and investigated when results fall outside limits set by test algorithms (Refer to procedures for **Ensuring Quality of Examination Results)**
Where EQA schemes are not available, quality of results is ensured by one or more of the following:

- Certified reference materials
- Comparing results gained against previously examined samples
- Exchange of samples with other laboratories

Refer to

HEM Lab	**Ensuring Quality Of Examination Results**	**NCI-CPD-HEM-QAU-TP008**
BMT Lab	**Quality Control in BMT Lab**	**NCI-CPD-BMT-QAU-TP009**

Post-examination processes (5.7)
All laboratory procedures ensure that results are reviewed by the authorized personnel before release and have been accepted as valid by the use of Internal Quality Control and maintenance procedures. For tests used to monitor a patient's condition, review of historical results is also mandatory to ensure that significant changes are identified and can be further investigated by the laboratory or clinician. (5.7.1).

Storage,retention and disposal of clinical samples 5.7.2

The laboratory has a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. In case of BMT Lab , the samples retained or stored are DNA samples, while in HEM Lab, there is no retention of Blood samples after it has been analyzed, and all samples are analyzed within the daily run and not retained

Retention time is defined by the Lab in each subunit, eg Flowcytometry: Blood and BM samples are retained for 48 hours at room temperature, in Immunogenetics Lab : DNA samples are indexed and stored in boxes at 4°C then at -20°C or -80°C for 5 years, and in Molecular Lab RNA samples are indexed and stored in boxes at -80°C for 5 months and DNA at 4°C then at -20°C for 2 years

Safe disposal of samples: Closed blood vacutainers and eppendorfs containing nucleic acids (DNA or RNA) are thrown into red biohazard bags according to local NCI regulations for waste management.

Refer to :

Handling, Storage, Retention And Disposal Of Clinical Samples Procedure NCI-CPD-BMT-QAU-TP011
Post examination processes of HEM Lab :Reporting and Release of Results Procedure NCI-CPD-HEM-QAU-TP005 (includes the Handling of Samples requirements)

Reporting of Results (5.8)

The CPD has determined, in consultation with its users, from other Clinical departments at NCI, procedures for reporting results including:

☐ The report
☐ The telephoned report
☐ The revised report
☐ Clinical advice and interpretation
☐ Mechanisms for informing the requestor if an examination that could compromise patient care is delayed .

The report is also used if a sample is rejected and relates to sample suitability against sample acceptance / rejection criteria or comments on sample quality that can affect the result (5.8.2).
Reports are issued for all samples received in the HEM and BMT Labs, and are formulated so that they are clear, and contain sufficient information for the user to interpret the results.
The report contains the following information where applicable:

☐ Examination procedure identification or the Equipment as in HEM results (5.8.3a)
☐ The name of the laboratory issuing the report(5.8.3b)
☐ Identification of the laboratory that issued the report by logo(5.8.3c)
☐ Unequivocal identification of the patient and location on each page(5.8.3d)
☐ Name and contact details of requestor (5.8.3e)
☐ Date of sample collection(5.8.3f)
☐ Type of sample(5.8.3g)
☐ Measurement procedure(5.8.3h)
☐ SI units(5.8.3i)
☐ Biological reference intervals and clinical decision values (especially critical results) (5.8.3j)
☐ Result interpretation(5.8.3k)
☐ Additional cautionary or explanatory notes(5.8.3l)
☐ Identification of examinations undertaken by research where no measurement performance is available (5.8.3m)
☐ When possible, the identity of the authorizer (s) of the report
☐ Date of report(5.8.3n)
☐ Page number to total number of pages(5.8.3o)

Release of Results (5.9)

Release of results are via manual validation.

The labs have a documented procedure that states the authorities based on certain characteristics and that only trained authorized personnel are able to do so.

Procedure documents, also highlight clinical decision values where the result must be immediately communicated to the requesting clinician and this is recorded using the telephone log (5.9.1).

Results issued as an interim report or given verbally are confirmed by the issuing a final report

by the laboratory on the LIMS and are relayed to the clinician to ensure that they have correctly understood the results. The laboratory advises clinicians not to make any clinical decision they make based on verbal or interim results and wait for the final report.

In the case of sample interferences (e.g. lipaemia or hemolysis) that may have an effect on the produced results, a comment is added to the report manually detailing this (can transfer from certain analytical platforms) (5.9.2).

The procedure for issuing a revised report (5.9.3) ensures:

☐ The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report (5.9.3a)

☐ The user is made aware of the revision

☐ The revised reports shows the date and time of the change and the person's responsible for the change

☐ The original report entries remain in the record whenrevisions are made

Refer to

Postexamination Processes Procedures

HEM Lab	**Reporting and Release of Results in HEM LAB**	**NCI-CPD-HEM-QAU-TP005**
BMT Lab	**Reporting and Release of Results in BMT Lab**	**NCI-CPD-BMT-QAU-TP010**

Laboratory Information Management (5.10)

NCI Information and Systems Manager is responsible for the management of patient data used to provide a service for Clinical Pathology Department Users. The HEM Lab utilizes a Laboratory Information System (LIMS) to record and store patient information. Access to electronic data is controlled and restricted by individual password security and assigned privilege rights, thus maintaining confidentiality and data protection . The system is backed up daily and the backups are safely and securely stored by NCI Information Technology department

Refer to

Laboratory Information Management Procedure NCI-CPD-QAU-TP010

List of Procedures and its compliance with ISO 15189: 2012 Standard Requirements

No	Title	Code No.	Clause	Issue Date.	Issue No.
	I. Management Procedures				
1.	Quality Policy Statement	F-NCI-CPD-QAU-QP007/01	4.1.2.3	**8-01-2018**	**01**
2.	Vision and Mission Statements	F-NCI-CPD-QAU-QM001/01	4.1	**8-01-2018**	**01**
3.	Organization Charts	F-NCI-CPD-QAU-QM002/02	4.1	**10-01-2018**	**01**
4.	Quality manual	NCI –CPD-QAU-QM-01	4.2.2.2	**10-3-2018**	**01**
5.	Laboratory Sample Collection Manual	NCI-CPD-QAU-LSCM-01	5.4.4	**20-02-2018**	**01**
6.	Laboratory Service Manual	NCI-CPD -QAU- SM-02	5.4.2	**15-1-2018/01**	**01**
7.	Laboratory Safety Manual	NCI-CPD-QAU- LSM- 03	5.2	**21-11-2017**	**01**
8.	Documents, Data and Records Control Procedure	NCI-CPD-QAU-QP001	4.3, 4.13	**28-1-2018**	**01**
9.	Quality Policy and Objectives Procedure	NCI-CPD-QAU-QP002	4.1.2.4	**2-12-2017**	**01**
10.	Internal Audit Procedure	NCI-CPD-QAU-QP003	4.14.5	**29-01-2018**	**01**
11.	Control of Non Conformity Procedure	NCI-CPD-QAU-QP004	4.9	**30-01-2018**	**01**
12.	Corrective and Preventive action Procedure	NCI-CPD-QAU-QP005	4.10, 4.11	**29-01-2018**	**01**
13.	Management Review Procedure	NCI-CPD-QAU-QP006	4.15	**26-01-2018**	**01**
14.	Quality Policy	NCI-CPD-QAU-QP007	4.1.2.3	**8-01-2018**	**01**
15.	Definitions of Total Quality Management	NCI-CPD-QAU-QP008	4.1	**8-01-2018**	**01**
16.	Effective communications Procedure	NCI-CPD-QAU-QP009	4.1.2.6 4.7 4.14.4	**24-02-2018**	**01**
17.	Customer Satisfaction Procedure	NCI-CPD-QAU-QP010	4.14.3	**8-01-2018**	**01**
18.	Service Agreements Procedure	NCI-CPD-QAU-QP011	4.4.1	**3-12-2017**	**01**
19.	Review of Service Agreements Procedure	NCI-CPD-QAU-QP012	4.4.2	**2-12-2017**	**01**
20.	Purchasing procedure	NCI-CPD-QAU-QP013	4.6	**20-02-2018**	**01**
21.	Code of Ethics in Laboratory Services	NCI-CPD-QAU-QP014	4.1.1.3	**15/01/2018**	**01**
22.	Contingency plan	NCI-CPD-QAU-QP015	4.1	**26-02-2018**	**01**

23.	Customer Complaint Procedure	NCI-CPD-QAU-QP016	4.8	**5-12-2017**	**01**
24.	Quality Indicators	NCI-CPD-QAU-QP017	4.14.7	**2-03-2018**	**01**
25.	Risk Management Procedure	NCI-CPD-QAU-QP018	4.14.6	**5-01-2018**	**01**
	II. General Technical Procedures for CPD Laboratories				
26.	Personal Management Procedure	NCI-CPD-QAU-TP-001	5.1	**1-1-2018**	**01**
27.	Training and Competency Assessment	NCI-CPD-QAU-TP002	5.1	**21-11-2017**	**01**
28.	Performance appraisal for Clinical Pathology Staff	NCI-CPD-QAU-TP003	5.1	**15-01-2018**	**01**
29.	Performance appraisal for residents and assistant lecturers	NCI-CPD-QAU-TP004	5.1	**16-01-2018**	**01**
30.	Accommodation and environmental Conditions Management (FOR BOTH)	NCI-CPD -QAU-TP005	5.2	**24-12-2017**	**01**
31.	Equipments Management Procedure for HEM	NCI-CPD-QAU-TP 006	5.3	**20/1/2018**	**01**
32.	Equipments Management Procedure for BMT	NCI-CPD-QAU -TP 007	5.3	**20/1/2018**	**01**
33.	Reagents and Consumables Management Policy (FOR BOTH)	NCI-CPD-QAU- TP 008	5.3.2	**20-12-2017**	**01**
34.	**Pre-examination Procedure Operating Procedure of Sampling Outpatient Clinics**	NCI-CPD--QAU-TP009	5.4	**20-02-2018**	**01**
35.	**Laboratory IT Procedure**	NCI-CPD-QAU- TP 010	5.10	**20-02-2018**	**01**
	III. Examination Procedures of HEM Lab				
36.	Complete Blood Count Procedure	NCI-CPD-HEM-QAU TP001	**5.5**	**20-12-2017**	**01**
37.	Coagulation Profile Procedure	NCI-CPD-HEM-QAU TP002	**5.5**	**20-12-2017**	**01**
38.	Verification Methods of CBC and Coagulation Profile	NCI-CPD-HEM-QAU-TP003	**5.5**	**25-1-2018**	**01**
39.	Ensuring Quality of Examination Results of HEM LAB	NCI-CPD-HEM-QAU-TP004	**5.6**	**22-01-2018**	**01**
40.	Post examination processes of HEM Lab Reporting and Release of	NCI-CPD-HEM-QAU-TP005	**5.7, 5.8, 5.9**	**20-02-2018**	**01**

	Results Procedure				
	IV. Examination Procedures of BMT Lab				
41.	Measurement of DNA index Procedure	NCI-CPD-BMT-QAU-TP001	**5.5**	**20-02-2018**	**01**
42.	Enumeration of CD34 positive progenitor stem cells	NCI-CPD-BMT-QAU-TP002	**5.5**	**14-02-2018**	**01**
43.	Immunophenotyping of Acute and Chronic Leukemia Procedure	NCI-CPD-BMT-QAU-TP003	**5.5**	**5-02-2018**	**01**
44.	Molecular HLA-A,B and DRB1 Typing (Reverse Sequence specific oligonucleotide probe) using strip assay	NCI-CPD-BMT-QAU-TP004	**5.5**	**12-02-2018**	**01**
45.	Molecular Class I & II typing (Luminex technology	NCI-CPD-BMT-QAU-TP005	**5.5**	**7-02-2018**	**01**
46.	Detection of JAK2V617F mutation	NCI-CPD-BMT-QAU-TP006	**5.5**	**15-2-2018**	**01**
47.	Fusion Gene Transcripts Detection by PCR	NCI-CPD-BMT-QAU-TP007	**5.5**	**25-2-2018**	**01**
48.	Detection of Nucleophosmin mutation	NCI-CPD-BMT-QAU-TP018	**5.5**	**20-02-2018**	**01**
49.	Method Verification of Immunogenetics	NCI-CPD-BMT-QAU-TP019	**5.5**	**12-2-2018**	**01**
50.	Method Verification of Fusion genes detection	NCI-CPD-BMT-QAU-TP020	**5.5**	**13-2-2018**	**01**
51.	Method Verification of JAK2V617F mutation	NCI-CPD-BMT-QAU-TP021	**5.5**	**21-02-2018**	**01**
52.	Method Verification of Flow Cytometry	NCI-CPD-BMT-QAU-TP022	**5.5**	**5-03-2018**	**01**
53.	**Quality Control in BMT Lab**	**NCI-CPD-BMT-QAU-TP009**	**5.6**	**20-02-2018**	**01**
54.	**Post-Examination Procedure of BMT Lab: Reporting and Release of Results**	**NCI-CPD-BMT-QAU-TP010**	**5.8 5.9**	**18-02-2018**	**01**
55.	**Post-examination Procedure Handling and Storage of Samples**	**NCI-CPD-BMT-QAU-TP011**	**5.7**	**14-02-2018**	**01**

Amendment History Table

No	Summary of amendment	Date	Issue No.