

DCN: QA-QP-01

REVISION NO: 01

EFFECTIVE DATE: 02-02-2020

REVIEW DATE: 12-01-2023

PAGE NO: 1 OF 7

SECTION: QUALITY ASSURANCE

TITLE/DESCRIPTION: Internal Quality Audit Policy

PURPOSE:

The Master Audit Plan designed for a specific clinical study consists of a combination of several QA activities designed to ensure quality and regulatory compliance, to define timelines, and to identify personnel. These activities may include the review of the regulatory documents such as safety and quality policies, 5's, Turn-Around-Time (TAT), review of standard operating procedures (SOP's), and clinical practices.

LEVEL:

All Divisions, Management Committee

DEFINITION OF TERMS:

Audit Master Plan - an action plan that documents what procedures an auditor will follow to validate that an organization is in conformance with compliance regulations.

POLICY:

- 1.) The Quality Assurance Supervisor shall create a yearly audit master plan approved by the President and CEO.
- 2.) The Master Audit Plan shall include standardized audit programs, tailored audit programs and compliance audit programs. Standardized audit programs, which are available for many different areas, can be used proactively to help an organization create its own internal compliance framework and internal audit program.
- 3.) The Master Audit Plan shall be disseminated or its copy be given to respective unit/sections/depart/divisions.
- 4.) The Internal Quality Auditor shall use the Audit Master Plan as the basis of the date of audit on the different areas in the hospital.

MASTER COPY

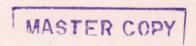
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DCN: QA-QP-01
REVISION NO: 01
EFFECTIVE DATE: 02-02-2020
REVIEW DATE: 12-01-2023
PAGE NO: 2 OF 7
SECTION: QUALITY ASSURANCE
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APPROVAL:

	Name/Title	Signature	Date
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Approved:	GENESIS GOLDI D. GOLINGAN President and CEO	7	2/18/2020





I	DCN: QA-QP-01
	REVISION NO: 01
	EFFECTIVE DATE: 02-02-2020
	REVIEW DATE: 12-01-2023
	PAGE NO: 3 OF 7
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PROCEDURE:

ANNOUNCED AUDIT

- 1. The Auditor shall make necessary preparations before the audit commence.
- 2. The QA Supervisor shall inform the areas to be audited not less than 14 days before the day of audit.
- 3. The Auditor shall select an internal audit focus for every member of the audit team.
- 4. The auditor shall inform the supervisor or the senior staff of the purpose of the audit.
- 5. The auditor conducts the audit on company's policies and standard operating procedures, required organizational practices and other statutory requirements or standards.
- 6. After the audit has been completed, the auditor briefly discusses the audit results, agrees when to address non-conformity/non-compliance findings, and submits a formal report within 72 hours post audit to the auditee.
- 7. The auditor shall inform the auditee that a follow-up audit to monitor compliance to corrected practices will be done.
- 8. The auditor concludes the audit process after the auditee affixed his/her signature on the audit form. By affixing his/her signature, he/she signifies that the audit results were discussed on his/her presence and that he/she fully understands and agrees to the findings.



QA- QP - 02 Rev. No. <u>01</u>

Date Effective: 02-02-2020



DCN: QA-QP-01

REVISION NO: 01

EFFECTIVE DATE: 02-02-2020

REVIEW DATE: 12-01-2023

PAGE NO: 4 OF 7

SECTION: QUALITY ASSURANCE

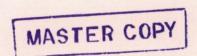
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UNANNOUNCED AUDIT²

Unannounced inspections more fully captured the true day-to-day conditions of the laboratories. The most common findings decreased over the time of the study for both announced and unannounced inspections, but to a greater degree for unannounced inspections. The results of this study show that implementing unannounced inspections in laboratory assessment programs may dramatically improve safety (Trucks, 2017).

POLICY

- 1. The TQD Quality Assurance shall conduct/perform spot or unannounced audit twice a year or more depending on the necessity or need or as the situation may warrant.
- 2. The unannounced audit shall follow the same format or process as followed or observed in the scheduled or announced Internal Quality Audit.





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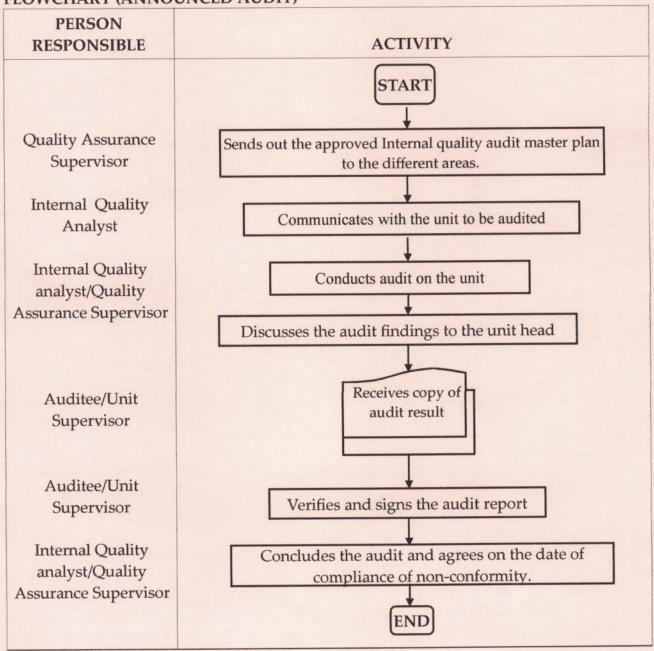
REVIEW DATE: 12-01-2023

PAGE NO: 5 OF 7

SECTION: QUALITY ASSURANCE

TITLE/DESCRIPTION: Internal Quality Audit Policy

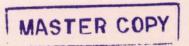
FLOWCHART (ANNOUNCED AUDIT)



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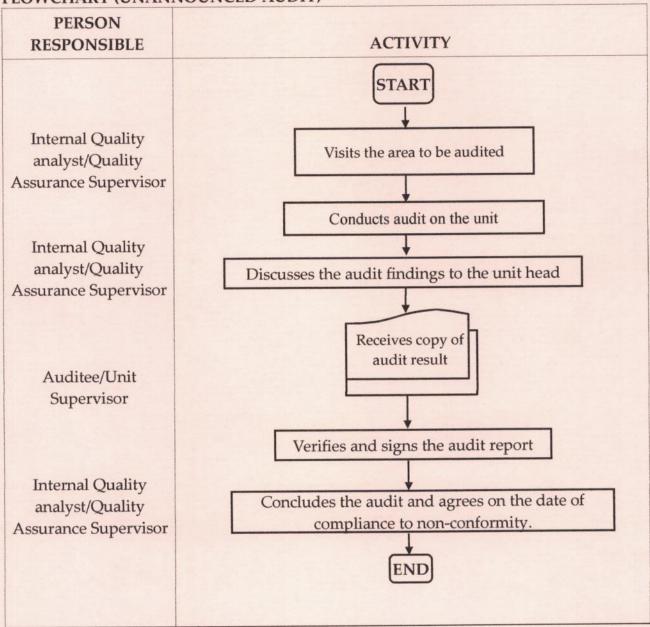
REVIEW DATE: 12-01-2023

PAGE NO: 6 OF 7

SECTION: QUALITY ASSURANCE

TITLE/DESCRIPTION: Internal Quality Audit Policy

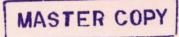
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REVIEW DATE: 12-01-2023

PAGE NO: 7 OF 7

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WORK INSTRUCTION:

Quality Assurance Supervisor

- 1. Creates the Audit Master Plan for approval by the President and CEO.
- 2. Inform the area to be audited not less than 14 days before the day of audit.
- 3. Heads the team of auditors during the audit.

Internal Quality Auditor

- 1. Conducts audit on the unit.
- 2. Discusses the audit results to the auditee.
- 3. Provides the auditee with the audit results.
- 4. Concludes the audit and agrees on the date of compliance to non-conformity.

Auditee

- 1. For announced audit, receives the Audit Master Plan and communication prior to the actual audit.
- 2. Receives audit report and provides date of compliance to non-conformity.
- 3. Verifies and signs the audit report.

DOCUMENTATION:

1. Audit reports

DISSEMINATION:

1. Section meetings, quality handbook, and RMCI intranet

REFERENCE:

¹ American Quality Assurance (2020). https://asq.org/quality-resources/quality-management-system. Retrieved: January 23, 2020

²Trucks, Holley M.; Theses and Dissertations: Public Health (M.P.H. & Dr.P.H.) College of Public Health 2017 An Assessment of the Effectiveness of Unannounced Safety Inspections Versus Announced Inspections in Academic Research Laboratories That Utilize Biological Hazards, University of Kentucky, holley.trucks@uky.edu

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