

Beaumont

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Laboratory Regulatory Agency Inspection

Document type: Procedure

I. INTRODUCTION:

The Laboratory may be inspected at any time by a regulatory agency. These inspections normally occur during the course of a hospital visit by State agencies such as the Michigan Department of Consumer and Industry Services (MDCIS) or the Michigan Department of Labor, also known as the Michigan Occupational Safety and Health Administration (MIOSHA). These agencies regulate safety and health in the workplace. Document Type: Procedure or Guideline

II. POLICY:

It is the policy of the Laboratory to cooperate with any governmental agency that has the authority to regulate any aspect of Laboratory operations. Hospital Administration is to be notified immediately of any inspections as described in this guideline.

III. PROCEDURE:

A. Preparing for an Inspection

1. Any records required by regulatory agencies shall be kept current and accessible at all times.
2. When there is notice that a representative from a regulatory agency will be in the Laboratory, an individual from Laboratory Administration will prepare for the arrival of the inspector by notifying all supervisory staff and the Chief Pathologist.

B. Conducting and Inspection

1. Upon arrival of a representative of any regulatory agency, Hospital Administration shall be immediately notified.
2. While in the Laboratory, representatives from regulatory agencies are accompanied at all times by a representative from Laboratory Administration who is familiar with the facility, operations, and applicable regulations.
3. Questions shall be answered in an honest, straightforward manner. Answers should be limited to the scope of the immediate question.
4. If the inspector chooses to take photographs, perform monitoring, or collect samples for analysis, the Laboratory should take duplicate photographs or collect duplicate samples in the presence of the inspector.

C. Inspection Follow-Up

1. Upon completion of an inspection, a summary discussion between the regulatory agency’s representative and appropriate administrative personnel should be encouraged. This will permit clarification of issues, where there is a difference of opinion.
2. If a citation is issued, copies of all associated documents should be forwarded to Hospital Administration.



Approval Signatures

Step Description	Approver	Date
Medical Directors	Jeremy Powers: Chief, Pathology	7/21/2023
Medical Directors	Muhammad Arshad: Chief, Pathology	7/19/2023
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