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Clinical Laboratory Accreditation

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Incident Management

•Overview•

Any laboratory must have a system in place to document errors, injuries, incidents, and near-misses. Documenting these instances creates a record of what happened and how it was handled or corrected, and allows the laboratory staff to discern patterns that may require a more substantial review of the laboratory's procedures. An incident management plan will describe in detail what types of situations require reporting and investigation, the steps to follow in collecting information and finding a root cause, and the parameters for notification of any internal or external individuals.

When evaluating which situations could be defined as an "incident," the laboratory must take the following into consideration:

- Does this situation risk a significant impact on the accuracy and reliability of test results?
- Does this situation have potential for a significant negative impact on patients or staff, particularly death or serious injury?

Any situation meeting the above criteria should be investigated so that the cause can be found and corrected. For example:

- Discovering that quality control has been out of range on the hematology analyzer for a week, and testing personnel did not notice.
- A patient sustaining an injury after slipping from a phlebotomy chair.
- A patient with a known alloantibody receiving a unit of packed cells that was not typed for the corresponding antigen.

• The Incident Management Plan•

The Incident Management Plan must be available to all laboratory staff, who should be trained on its application. The plan itself, in its written procedures and/or forms, must address the following:

- How to recognize or identify a potential incident
- Identification of responsible parties having the requisite knowledge and authority to conduct the necessary investigation, evaluation, analysis of medical significance, and resolution of identified incidents
- Steps to be taken in the investigation and evaluation of an incident
- Consideration of impact on patients, staff, and clients, during the past, present and future
- Implementation of corrective measures to prevent occurrences
- Documentation requirements associated with the investigation and outcome

The Incident Management plan must direct the efforts of the laboratory staff in the identification, evaluation, and resolution of laboratory incidents. Note that some types of incidents may need to be reported to external entities such as the Food and Drug Administration. The plan should indicate when this is necessary, and how to initiate that process.

● Investigation and Resolution ●

A complete and thorough investigation must be taken in response to all identified incidents. Copies of all records reviewed during the investigation should be retained for at least two years. It is critical to ensure that the laboratory has identified the true root cause of any incident, in order to make appropriate corrections to prevent a recurrence. There are many different ways to perform this sort of analysis, but one simple approach that can be used is the "five whys" concept. This involves asking why something happened, and then continuing to ask why until the root of the problem is identified. It will not always take five "whys" to get to the root, but it is important to continue asking until you've found the source of the issue. For example, using one of the incidents above:

- Why did the patient fall out of the chair?
  - The wheels were left unlocked and the chair moved as they sat down.
- Why were the wheels unlocked?
  - A staff member had cleaned and disinfected the chair and in doing so accidentally unlocked the wheels.
- Why didn't the staff member in question lock the wheels after cleaning?
  - They were not familiar with the locking mechanism on this type of chair.
- Why wasn't the staff member trained in the chair's features?
  - This was not part of the new hire initial training checklist.

As you can see, this process eventually leads to a specific root cause that can be addressed such that the incident is unlikely to reoccur. If we stopped asking "why" after the first two questions, perhaps this person would be trained in operation of the chair's locking mechanisms. But by going further to see that perhaps this should be part of every new staff member's initial training, this laboratory is ensuring that all future staff will also receive that training. It is important to remember that this process is not intended to direct blame at any individual. In general, an incident indicates a need for improvement in one of the laboratory's procedures, forms, or workflow, so that staff will not make the same error again.

Once the investigation concludes with a root cause, the laboratory should develop a corrective action plan to address the source of the incident. The action plan, along with any training associated with it, should be documented and retained with other Quality Assessment records. Be sure to always share the results of any incident investigation with applicable staff, so that the root cause is understood and that the corrective action is clear to everyone.

The final step is to follow up on the corrective action plan within a reasonable amount of time, in order to assess whether the corrective action was adequate. This follow up assessment should also be documented and retained.

• Conclusion •

Every laboratory needs to have a procedure in place for identifying situations that can potentially affect patient results or cause harm to patients or staff. A thorough investigation, action plan, and assessment of the plan's effectiveness can help to make these incidents less frequent. This will lead to better quality results and a safer laboratory.

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