PROPOSAL FOR ESTABLISHMENT OR MODIFICATION TO TNI STANDARD

Expert Committee or group requesting the establishment or change to the Standard: Quality Systems

Proposal Date: 7/16/2015

CSDEC Approval: __/__/__

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<th>TNI Volume</th>
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Nature of the standard to be established or the change to the existing standard proposed:
A definition of the term 'Lot' is proposed to be added.

Justification or need for the standard or the change in the standard:
The term Lot has been added to the PT Modules. The term is important in its ability to define what a second source is. By using the same term in both the PT and Labortory Modules, consistency across the Volumes will be maintained.

How is the proposal an improvement over the existing standard:
The term was not previously defined. By its definition, the Standard will address issues that have arisen regarding second source verification of calibration curves, as well as maintaining consistency across multiple Volumes.

Any potential conflicts developed upon development of the standard or the proposed change to the standard? Yes (Y) or No (N)

Any potential obstacles to implementation by ABs? Yes (Y) or No (N)

Signature of proposal representative: 7/16/2015

Date: