## Instructions on the use of the Internal Audit checklist

This checklist is provided to assist in the conduct of an internal audit as required by TNI V1M2 4.14. The checklist is not a detailed version of the standard itself, but reminds the auditor of important elements to check. Assumptions have been made in the development of the checklist. The foremost assumption is that the laboratory has developed all required and most other indicated Standard Operating Procedures stated in the Standard. As a reminder, the second worksheet of the checklist contains all references in the Standard to the need for either or both a policy and procedure. The Standard states in V1M2 4.8.2.5 that the laboratory is to have written procedures for all activities and that this is not limited to just analytical SOPs. The third worksheet provides a list of expected SOPs meeting the requirements of 4.8.2.5 and indirectly stated in the Standard.

**In all cases, the Standard language is the requirement, not the contents of this checklist. In all cases where the checklist language differs from the Standard language, the Standard is to be followed.**

## Review is on Actions and Records

The expectation is that all documents exist, and it is likely that only a few of these indirectly specified documents are missing. The focus is on conformance to the existing SOPs and that evidence via records are available and complete. The checklist reminds what information is to be collected and what records are needed.

## Expansion of the Checklist

The checklist only provides a single line for each question. Since the goal is to review all activities, It is likely that more than one process or analytical procedure will be under review. You may wish to consider creating copies of various worksheets or expanding to the right on any worksheet. You may wish to create additional copies of the checklist workbook as well.

## Conducting the Audit

The Standard requires that the audit is to be completed as established by the Internal Audit SOP (annually is suggested not required). Consider breaking the audit into sections and conduct them at regular intervals, such as quarterly. As stated above, the goal is to review all laboratory functions.

## Concluding the Audit

Once you have completed your review, you need to write up your findings. Although your report does not have to be formal, it should state the following.

* Citation of the specific Standard or SOP section dictating the action
* Observations indicating a failure to conform with the above. Cite as many examples as possible, but if there are many, you may note significant examples.

You do not need to devise actions at this point. Actions are part of the Corrective Action SOP, which should be applied to the findings. As stated in V1M2 4.11.7, it is necessary to determine if the finding represents a systemic failure before beginning Root Cause analyses. Many findings may simply be human error and not part of a systemic failure.

## Planning the Next Audit

At this time, begin planning the next audit cycle. If you broke the audit into sections, you may wish to keep the same schedule.