



TNI QUALITY MANUAL TEMPLATE TRAINING

FSEA Spring Meeting 5/25/2011

Quality Manual Template
Subcommittee





AGENDA

Introductions	11:00 – 11:05
Instructions	11:05 – 11:35
Complete a Section	11:35 – 11:50
<ul style="list-style-type: none">- Section 13: Improvement- Section 14: Corrective Action	
Wrap-up	11:50 – 12:00





Disclaimer

No template, no matter how complex, can guarantee a finding-free audit because the template cannot predict how you operate your laboratory, nor predict the quality and quantity of other required information you have available outside of the template.





Disclaimer Part deux

Every effort was made to ensure the accuracy of the information provided, but the laboratory has final responsibility for the accuracy of their *Quality Manual*.

Use of this Template is not a requirement for FDoH accreditation. It is just a tool to assist in the preparation of your quality manual.





Instructions





- You can create your *Quality Manual* by:
- using example text,
 - modifying example text to accurately reflect your situation,
 - creating your own text, or
 - deleting or labeling sections that don't apply as "not applicable."





Getting Started

- You need to set your Microsoft Word Options to allow you see “hidden text”.
- Save a copy of the original template for safe keeping.
- Begin editing the manual.
- Customize the tools that have been collected and posted on the TNI website.

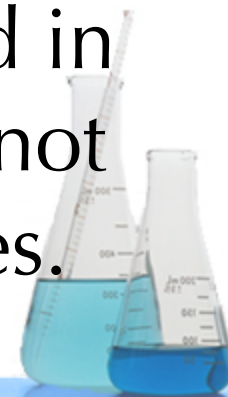




Getting Started

Passages that require you to <insert> something are highlighted in yellow and provide a hint as to what you might need to add to the text to make your manual TNI-compliant.

Notes to you, the writer, are highlighted in gray and can only be seen if the text is not hidden. There are a number of examples.





Hints

Your entire management system does not need to be specifically documented in your *Quality Manual*. It is a road map for your system and you may refer to SOPs and policies as appropriate.

Be cautious to not repeat information between SOPs, policies and the *Quality Manual*.





Hints

See Section 4.2.8.3 for items that must be in the *Quality Manual* and Section 4.2.8.4 for items that can be referenced or included in the *Quality Manual*.

Identification of the laboratory's approved signatories must be included in the *Quality Manual* but audit procedures may be referenced.





Manual Organization

The template is modeled after the TNI Standard - Volume 1 : Module 2.

Sections 1,2, 3 of the Template:

- Section 1 – Introduction, Scope, Applicability
- Section 2 – Normative References
- Section 3 – Terms and Definitions





Manual Organization

The template is modeled after the TNI Standard - Volume 1 : Module 2.

Sections 4-19 of the Template:

- Section 4 – Management Requirements

Sections 20-28 of the Template:

- Section 5 – Technical Requirements

Appendices A-K of the Template:

- Detailed Examples and Modules 3-7





Manual Organization

There is a separate file for each section of the template. This will make updates simpler.

When a section is updated – also update Section 1 (cover page with signatures) and Section 2 (Table of Contents).





Manual Organization

The Effective Date on the cover of the *Quality Manual* must be the same as the most recent effective date on any section included in the *Manual*.

When establishing effective dates, consider the date of the last signature on the cover and training and implementation time.





Editing

Default Font Style and Size

Verdana, 10pt

Inserting Text in the <insert> Field

Enter the text before the highlighted yellow section and then delete all the yellow highlighted information.





Editing

Changing the NOTES to Regular Text

Highlight the text you want to use and then copy and paste it into a section with normal text.

Text that is underlined with small dots is “hidden”. Click on Format and Style to clear the hidden text formatting if needed.





Editing

Outline Numbers and Indents

If addition of text causes problems, remember there is no requirement to number the sections. You can delete the numbering or simplify it.

The instructions have additional details for more experienced Word users.





Editing

Using Find and Replace

Use the replace function to change terms or titles that are different between the template and your organization (i.e., Quality Manager or Quality Systems Manager).





Editing

Include Your Laboratory Name in Footnote

Use the Header/Footer option to insert your laboratory name.





Editing

- Note: The footer below can be customized to the exact title of your Quality Manual document or to include your laboratory name. To modify the footer, click on “View, Header and Footer”. Your manual will jump to the top of the page, showing the header. A menu bar will have also popped up.





Editing

- To switch to working with the footer instead of the header, click on the icon on the menu bar that looks like a piece of paper with two yellow rectangles – one in front of the paper, and one behind the paper. This is the toggle switch between the header and the footer. Click it until you are looking at the bottom of the page and the footer. Click inside the footer box, and type whatever you want . To finish, simply click the “Close” button on the menu bar.





Example: Section 13

Improvements





Section 13

A laboratory must strive to improve the effectiveness of its management system through the use of its quality policy, audits, corrective and preventive actions, management reviews, etc ...





Section 13

A few measureable items that can be used to demonstrate improvement:

- Regulatory, client and internal audit findings.
- PT performance.
- Internal blind study performance.
- Corrective actions.
- Customer complaint resolutions.





Example: Section 14

Corrective Action





Section 14

- ISO language – Establish a policy and a procedure
- ISO language – Cause analysis
- ISO language – Select and Implement Corrective actions
- ISO language – Monitor the corrective actions
- ISO language – Additional audits





Wrap Up





- The template is distributed by email. If you have not received a copy, please make sure to give your email address to *Ilona Taunton* before you leave.
- Tools will be continually added to the website for your use. Improvements should start appearing in early June 2011.





- Use the Standards Interpretation Request (SIR) process to ask questions about the standard itself. (*Make sure the question has not already been asked.*)
- Contact Ilona Taunton at ilona.taunton@nelac-institute.org with questions about the template.





- Thank-you to everyone who helped in the planning, writing and editing of this template.





- The examples were provided by laboratories (large and small) and consultants all over the country. Thank-you for your generosity. We want to continue to build this library of tools and welcome any examples submitted (*submit to Ilona Taunton*).

