

Process for Creating Guidance

Alfredo Sotomayor, Chair Policy Committee Forum on Laboratory Accreditation August 9, 2010



Policy 1-105 "Creation and Use of Guidance"

- Sets the tone
- Defines guidance as non-mandatory
- > Explains proper use
- Requires disclaimer
- > Authorizes creating a procedure for crafting guidance
- > Approved by Policy Committee and TNI Board



SOP 1- 105 "Process for Creating Guidance"

> Anchored by POL 1-105

- Reiterates unenforceability of guidance; re-emphasizes disclaimer
- >Establishes stepped process
- > Approved by Policy Committee
- Will be presented for concurrence to TNI Board





"Guidance is non-mandatory information, rendered in any medium intended for communication, which explains, illustrates, or summarizes a subject without imposing requirements, establishing policy, or becoming a standard operating procedure."



Exclusions

- Some informational material produced by TNI is dynamic or follows alternative approval processes. The SOP does not apply to:
 - Answers given by programs to frequently asked questions (FAQs).
 - Responses to requests for TNI Standards interpretations.
 - Presentations delivered by TNI members, when those presentations are reasonably understood not to constitute guidance.



Use of Guidance: "Facilitates" NO

> Helps
> Suggests
> Explains
> Unenforceable

YES

- Dictates
- Demands
- > Proselytizes
- Enforceable



The Process I: Establishing Need for Guidance

- Any one can suggest creating guidance.
- Committees, executive committees, councils, and TNI Board review and decide guidance is needed.
 - > Only these groups can develop a proposal for creating guidance.



The Process II: Developing Proposal for Guidance

- Authorized group uses form to present proposal for guidance
 - Crafters
 - > Purpose
 - Communicates, clarifies, helps implement TNI Standard
 - Justification for creation
 - > Parties reviewing guidance
 - > Levels of technical review



Technical Review

- A review undertaken by the originator of guidance and any designated group to determine the accuracy and utility of the content of guidance.
- Two levels of technical review:
 - Minimal
 - Comprehensive
- Proposals that communicate, clarify, or help implement a TNI Standard will likely receive a comprehensive technical review.



The Process III: Reviewing Proposal for Guidance

- Policy Committee reviews all proposals for guidance.
- If justified:
 - Sends OK to originator
 - Identifies any additional conditions for approval
 - Specifies level of conformance review



Conformance Review

- A review undertaken by the Policy Committee or its designee to determine whether proposed guidance meets and does not exceed the definition of guidance.
- □ Two levels of conformance review:
 - Minimal
 - Comprehensive
- Proposals for creating guidance that communicates, clarifies or helps to implement a TNI Standard should receive a comprehensive level of conformance review.



The Process III: Reviewing <u>Proposal</u> for Guidance (cont.)

If review determines guidance is not justified, Policy Committee informs originator and recommends:

- Develop Policy
- > Develop SOP
- Modify or create Standard





Review and Approval of Guidance

- Guidance goes back to Policy Committee after completed and approved by creators.
- Policy Committee or designee performs conformance review.
 - If guidance is in conformance, Policy labels it "Official TNI Guidance" and clears it for publication.
 - If guidance is not in conformance, Policy returns to originator with suggestions for revision, and can be resubmitted for reconsideration.



Drafts of Guidance

- May be circulated and available if labeled as such.
- Possibility for having a place in the TNI Website for "unofficial" guidance.





Be Very Afraid? or Don't Worry, Be Happy?





Final Thoughts

- Many of our constituents tell us guidance is needed.
- Many of our constituents are afraid of guidance being misused.
- We will meet in between the dark and the light.
- We will see how this works, and if not, we will retool.