

## Summary of Non-governmental Accreditation Body Working Session

August 8, 2016 Garden Grove, CA

Alfredo welcomed everyone to the meeting. The members of the TNI Non-governmental Recognition Committee (TNRC) and the NGAB workgroup seated at the table were:

Alfredo Sotomayor, NGAB workgroup leader  
Steve Arms  
Cheryl Morton  
Jerry Parr  
(Jim Todaro was absent)

Judy Morgan, TNRC Chair  
Daniel Lashbrook  
(Kim Watson, Yumi Creason and Marlene Moore were absent)

Ilona Taunton, Lead Evaluator  
Kristin Brown, Evaluation Team Member  
Carl Kircher, Evaluation Team Member (absent)

### Update since Tulsa

Applications were received from NGABs in mid-August 2015 and reviewed by the Lead Evaluator and one team member with site visits during February and March, 2016. Observations of assessments were performed during March, April and June, 2016.

Team member Carl reviewed the APLAC or IAAC evaluations of the NGAB applicants and found them to be very thorough. Findings from the NGAB applications were primarily in areas where the TNI standard goes beyond the ISO 17011 requirements.

Plans are to announce all recognitions as a block, unless one of the organizations requires some extended time to complete its corrective actions.

Several "lessons learned" from this initial set of evaluations were that TNI needs an appeals process for its evaluations, that confusion of terminology occurs and lastly, that the standard or the Technical Review checklist (part of the application) should highlight the TNI-specific requirements. (NOTE: these are clearly identified in the Standard itself, as non-italicized text.)

One participant inquired about the frequency of renewal evaluations. For now, a three year cycle is envisioned, consistent with the NELAP evaluations. (NOTE: The three years is driven by the EPA drinking water program requirement for site visits every three years.)

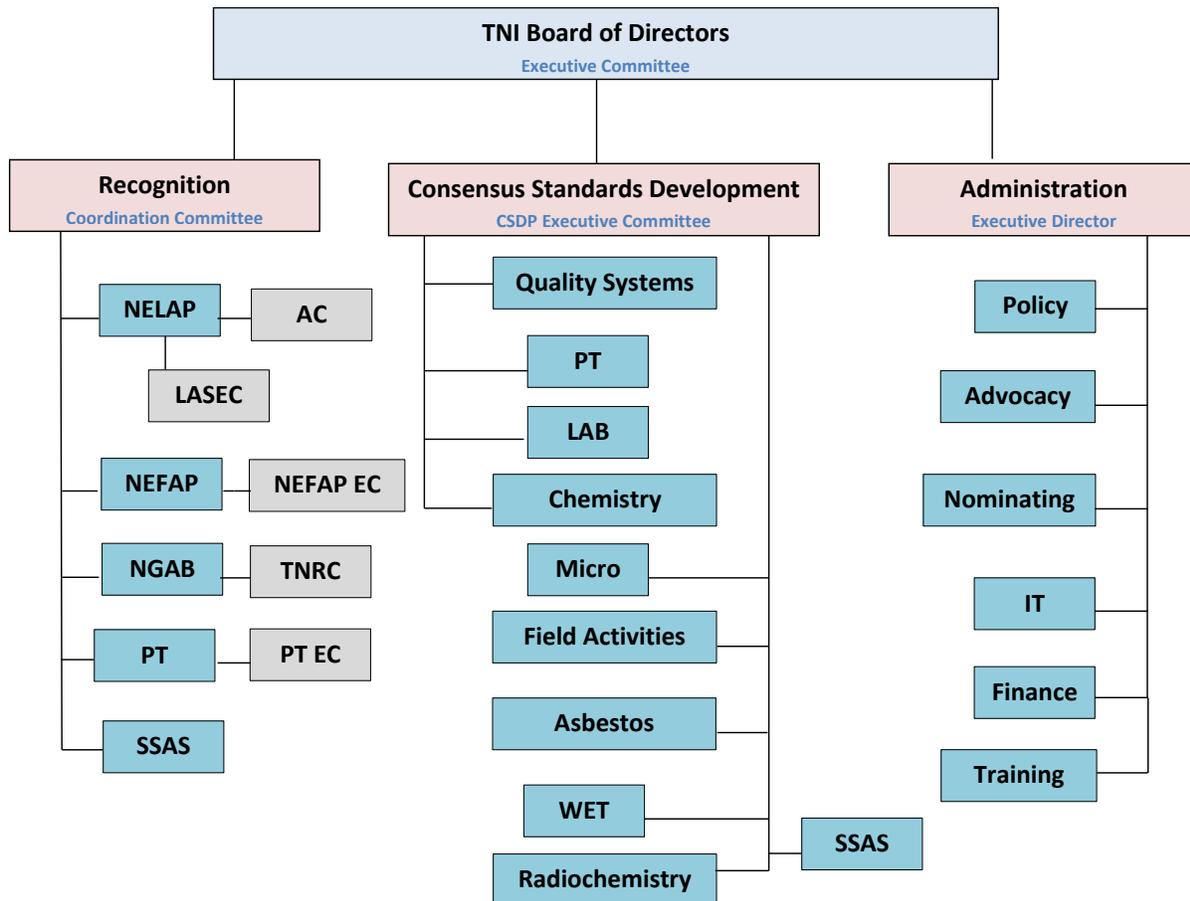
### Organizational Location within TNI (see outline of PowerPoint Presentation in Attachment 1)

The NGAB activity is currently attached to TNI's Board of Directors. A complaint was filed last year, claiming that the NGAB recognition was a "core program" of TNI and should have a separate structure as other core programs do. The outcome of the investigation of this complaint was that the NGAB activity is NOT a core program but the investigatory team did recommend a shift of its organizational location away from the Board.

Options presented at that time were for the NGAB activity to remain subordinate to the Board, or else to be placed under the Laboratory Accreditation Systems Executive Committee (LASEC) but separate from the NELAP Accreditation Council (AC.) The initial decision was to leave it under the Board until the initial recognitions were announced. The Board agreed that long-term oversight belongs elsewhere and charged the NGAB Working Group and the TNRC with finding a solution.

Both groups discussed and are proposing the possibility of consolidating all recognition activities in one place – this program, NEFAP, the PT provider accreditors, SSAS, and NELAP, while acknowledging the need to maintain separation for the governmental ABs. To help accomplish this, the groups considered forming a new coordinating committee to host the recognition activities, that would ensure consistency of policy and management and be composed of representatives of all of the recognition activities. This coordinating committee would not be an Executive Committee and would have no authority over the individual recognition decisions. Each individual entity would continue its non-recognition activities as before. The remaining parts of TNI, the Consensus Standards Development Program (CSDP) and the Administrative committees, would remain as they are.

The following graphic from the attached PowerPoint is shown here for clarity:



At present, the TNRC serves only the NGAB activity, while the NEFAP and PTP accreditors have separate recognition structures. Several alternative structures were proposed (see graphics within the

powerpoint outline in Attachment 1), where the coordinating committee could host a single recognition committee or the recognition function could be handled by an Accreditation Systems Executive Committee (ASEC, similar to the current LASEC but with a charter covering all accreditation programs, not just laboratories.) This recognition group (however named) could issue certificates to approved ABs as well as recommending the evaluation teams to the individual programs, if desired, while the NELAP and TNRC/NGAB activities could remain independent of that recognition committee, yet still be within the coordinating sphere.

Comments from the audience participants are noted below:

The workload for the proposed ASEC could be excessive for volunteer members.

The cross-over between governmental and non-governmental ABs may get further complicated if the states now considering applying to be NEFAP ABs do so.

Considering NELAP recognition for NEFAP ABs could create a perception that NEFAP governmental ABs have a less rigorous evaluation than the non-governmentals that have undergone evaluation by one of the regional ILAC signatories (APLAC or IAAC).

Imposing a new recognition structure on the two existing programs (PTP Executive Committee and NEFAP) could bring chaos.

A separate accreditation to ISO 17011 is not equivalent to being an ILAC signatory, but that concept might be useful to states applying to NELAP.

Implementation of such a restructuring could take more time than envisioned.

Specific discussion of the implications for accreditation of drinking water laboratories would be needed.

Use of LAMS by NGABs needs to be specifically considered. Currently all NGAB applicants do submit data to a similar DoD database, that tracks accreditations by method but not by analyte, and they find it to be a huge maintenance issue; they may not want to report by analyte into LAMS.

TNI's Database Administrator could provide a webinar for the NGABs, and not simply a link on the NGAB webpage. Dan noted that the LAMs listings are updated as often as the ABs choose, but at least bi-weekly, and that updating analytes is typically done with a CSV file (from spreadsheet) but that any relational database would serve the purpose.

At this point of the discussion, the scheduled break time came, and the workgroup met as a "working session" afterwards.

### **Working Group Session**

Present were Alfredo, Judy Morgan, Steve Arms, Ilona, Cheryl Morton, Daniel Lashbrook, Dave Speis, Jerry Parr, Carl Kircher, Ken Lancaster and Mike Shepherd.

Alfredo reflected that the proposed recognition coordinating committee concept seems viable, that there were no objections raised to such a structure. He noted that a few of the concerns expressed were puzzling but others helpful.

Another concern expressed here was that the small programs (NEFAP and especially PTPAs) will “get lost” in the larger structure designed to accommodate both the NGABs and the NELAP AC.

If the evaluation function falls primarily in the coordinating committee, which is envisioned since the same set of non-governmental ABs are recognized in every program except NELAP (at least, for now), then we need to create a Technical Review checklist based on ISO 17011 with “color-coding” of the additional requirements for each of the separate programs, so that a single AB could be evaluated for any or all of the possible recognitions available to it.

A suggestion emerged that the coordinating committee handle all evaluation applications.

While “recognition” is not an entirely satisfactory term, nothing better has emerged, and just “coordination” is inadequate to describe the committee’s scope of responsibility. If each of the current programs maintains its current structure within the coordinating committee, there will be recognition structures associated with each program/activity:

NELAP – the AC and LASEC

NEFAP – the Executive Committee

NGAB – TNRC

PT – the Executive Committee

SSAS – (however its providers are approved)

The functions of the coordinating committee would be:

- Administering the AB application process
- Promoting consistency among the various activities
- Preparing/maintaining checklists from the individual programs

An alternative name arose, cooperation committee. However named, recognition functions would fall under the individual programs’ current structures, although under the larger umbrella of the coordinating committee, perhaps could be described as “sponsored” by the coordination/cooperation committee.

Two additional issues were raised but not resolved. First, that the revisions to ISO 17025 and 17011 that are underway will need to be incorporated into TNI’s standards in the foreseeable future, so that all checklists, SOPs and policies regarding recognition and accreditation activities will require re-examination and probable revision. Also, the TNRC will have only limited resources, and would benefit from having the coordinating committee involved with preparing such documents. Participants also noted that SSAS also needs to remain part of the CSDP as well, due to its dual role.

### **Next Steps**

Starting with the NELAP AC, and then the Board, the proposed new structure needs to be shared with all affected groups within TNI.

For the next meeting of the working group, specific tasks will be to review the organization chart and proposed structure as revised from the discussions at conference, and discuss how to approach the NELAP AC, since its concurrence will be vital to implementing such a change.



## **Attachment 1 – Outline of PowerPoint Presentation with Graphics**

Update on Non-Governmental Accreditation Bodies

Judy Morgan, Chair, TNRC

Alfredo Sotomayor, Chair, NGAB Working Group

### **Overview**

TNI began developing the process to recognize NGABs in 2013 with the formation of the NGAB working group chaired by Alfredo Sotomayor.

In 2014, the TNI Board appointed the TNI Non-governmental Accreditation Body Recognition Committee (TNRC) to approve NGABs according to the evaluation SOP.

These two groups have been working jointly and are very close to full implementation of the program.

### **NGAB Working Group**

Members

Alfredo Sotomayor, Chair

- Steve Arms
- Kristin Brown
- Marlene Moore
- Cheryl Morton
- Jim Todaro
- David Speis
- Jerry Parr and Carol Batterton, Staff Support

### **TNI Non-Governmental Accreditation Body Recognition Committee (TNRC)**

Judy Morgan, Chair

- Daniel Lashbrook
- Marlene Moore
- Kim Watson
- Yumi Creason
- Jerry Parr and Carol Batterton, Staff Support

### **Activities to Date**

Developed Evaluation SOP for NGABs using the NELAP and NEFAP evaluation SOPs as a model

Appointed a Lead Evaluator (LE)

Posted SOP and application form on TNI website under TNI Board tab

Held evaluator training (live and webcast)

Established budget and fees for program

Designed logo for NGABs and laboratories

### **Activities to Date**

Began accepting applications mid-August

- Received three applications

Formed evaluation teams

- Lead evaluator
  - ✦ Ilona Taunton
- Team members
  - ✦ Kristin Brown

✦ Carl Kircher

Scheduled evaluations for February and March

### **Update on Recognitions and Lessons Learned**

Ilona Taunton, Lead Evaluator

Timeline UPDATE?

ACTIVITY

Accept applications

Conduct on-site evaluations

Conduct onsite observations

Recommendations to TNRC

NGAB Recognitions

DATE

Aug-Sept. 2015

February-March 2016

Summer 2016

Summer meeting 2016\*

### **Location of TNRC in TNI**

#### **Background:**

Some state accreditation bodies (AB) cannot allow an NGAB to be a member of the NELAP AC

NGAB working group recommended that TNRC report directly to the Board

- Provided direct oversight by TNI Board for a new program
- Minimized conflict for some members of the NELAP AC

Location of TNRC in TNI

#### **Background:**

Complaint alleged that NGAB recognition constituted a core program

Investigation team disagreed, but recommended appropriate organizational placement of TNRC

TNI Board directed NGAB working group to prepare a concept paper outlining options for placement of NGAB recognition activities within TNI's organizational structure

### **Location of TNRC in TNI**

TNRC and NGAB working group met jointly and determined possible options for organizational alignment of the TNRC for NGAB recognition

### **Location of TNRC in TNI**

#### **Options considered in Fall 2015:**

Leave the TNRC in its current location reporting to the TNI Board of Directors

Place the TNRC under the LASEC, but separate from the NELAP AC

For future discussion:

- Group all recognition and accreditation activities under one program
- Group all recognition and accreditation into regulated and non-regulated programs

#### **Recommendation**

Place the NGAB recognition activities under the LASEC, but separate from the NELAP AC

Leave TNRC in its current location reporting to the TNI Board until after the first group of NGABs is recognized and then move to the new structure.

### **Results (not)**

At least one member of the NELAP AC had strong objections to placing the TNRC under the LASEC.

The TNI Board had objections to placing the TNRC under the Board.

The NGAB working group was directed to revise its charter and begin working on a new plan to combine all of TNI's recognition activities into one section of TNI.

### **How do we organize this?**

#### **New Charter**

Mission:

The NGAB Working Group in cooperation with The Non-Governmental Accreditation Body Recognition Committee (TNRC) will develop a plan to combine all of TNI's non-governmental accreditation body recognition activities under one organizational umbrella. The Working group will propose timelines to accomplish this organizational change

#### **Objectives**

Develop a plan and organizational structure to place non-governmental accreditation body recognition activities under one organizational umbrella within TNI.

Establish timelines for developing the plan and implementing this re-organization.

Develop any SOPs and procedures necessary to implement the new structure and ensure that the TNRC is anchored within the structure.

Work in cooperation with other TNI accreditation body programs to ensure consistent implementation of the new structure.

#### **Milestones**

Present preliminary recommendations for reorganization at summer meeting in Orange County, CA, 2016

Present final recommendations for reorganization along with draft SOPs, SOP revisions, and Policies to TNI Board at January 2017 meeting in Houston, TX 2017

Provide progress reports to TNI Board at each monthly meeting

#### **Considerations**

The working group will:

- Consult with the NEFAP and the LASEC during the development of the organizational plan.
- Identify opportunities for improvement of current processes during development of the new organizational plan.
- Seek to minimize financial impact on TNI in development and implementation of the new structure.

#### **Guiding Principles**

All recognition activities should be placed under one group.

Dividing regulatory and non-regulatory activities would create duplication.

Any new structure should provide opportunity to expand without another reorganization.

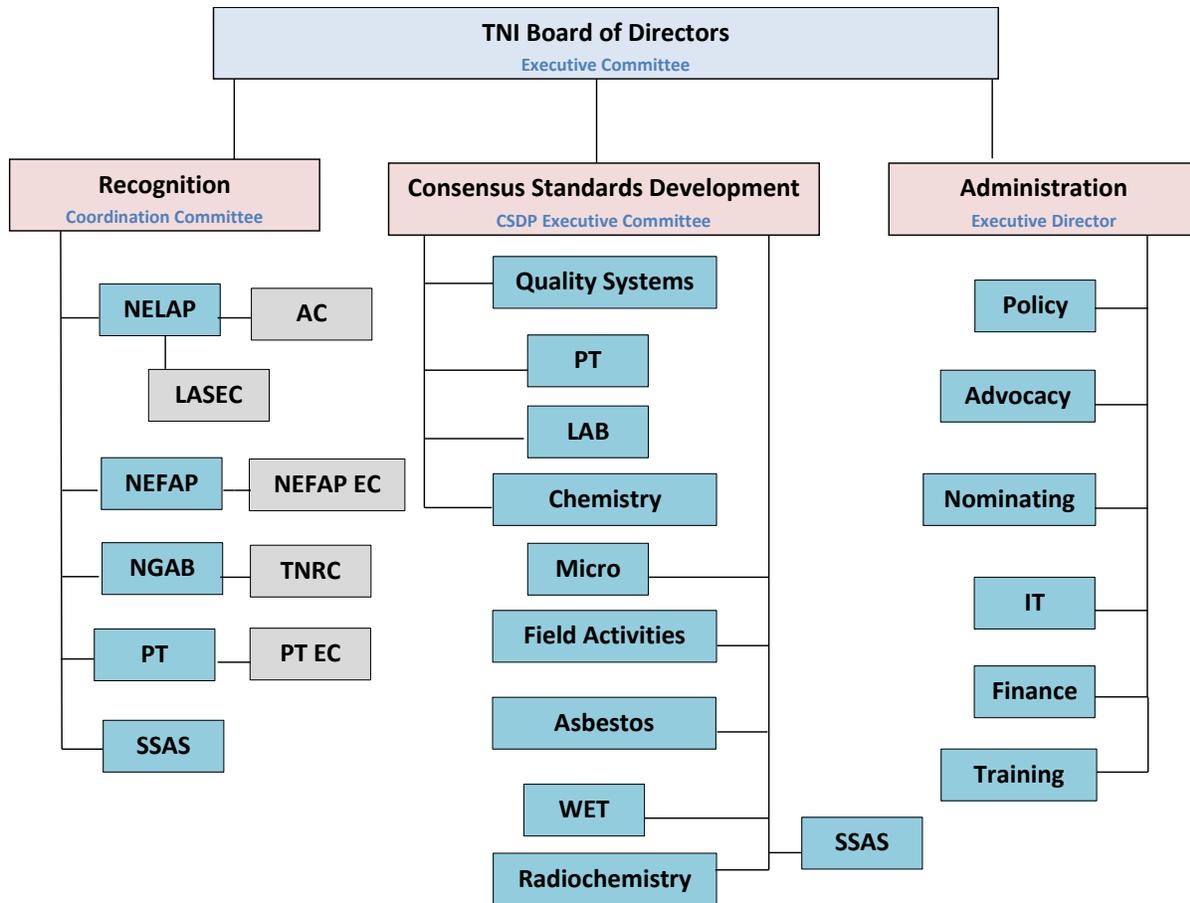
Organization should be considered functional or relational, not hierarchical.

### For Consideration

TNI's organization structure should be divided into three main components:

- Recognition
- Consensus Standards Development
- Administration

### Organization Chart



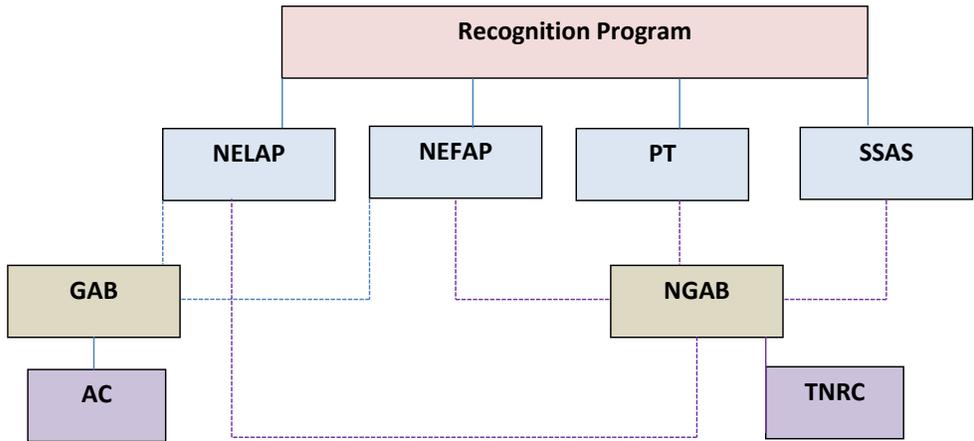
### Discussion

Establishes three major programs representing core TNI activities.

Maintains all current committees.

Creates a "Recognition Coordination" committee to maintain consistency in all recognition activities.

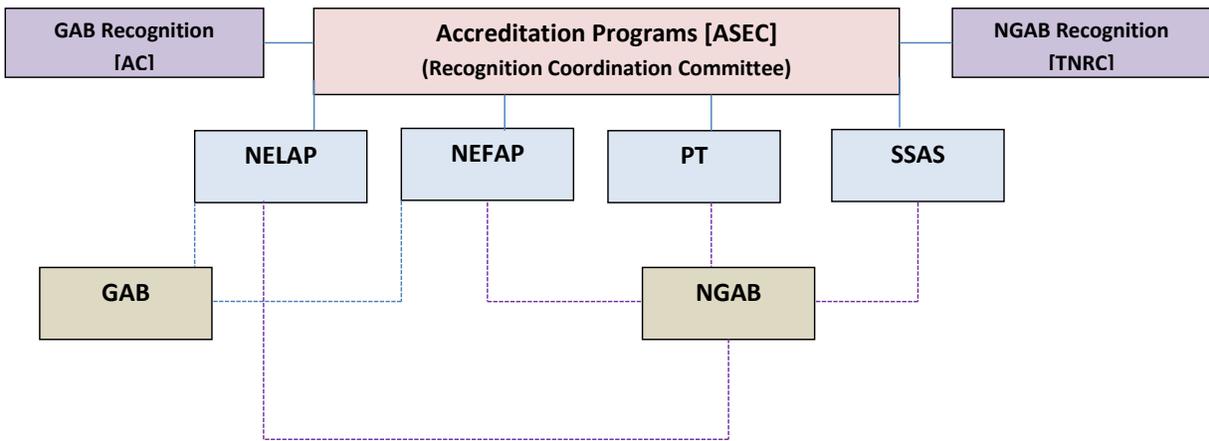
**Another Look – Recognition**



**Discussion II**

- One recognition program
- Four core activities
- Two key types of players:
  - GABs, NGABs
- Different recognizers:
  - AC, TNRC

**Another Look – Accreditation**



**Discussion III**

- Collect all accreditors under a single program.
- Expand the role of the LASEC.
  - Rebrand it ASEC.
- Retain separation of TNRC and AC.
- Establish coordination committee.

## Other Thoughts

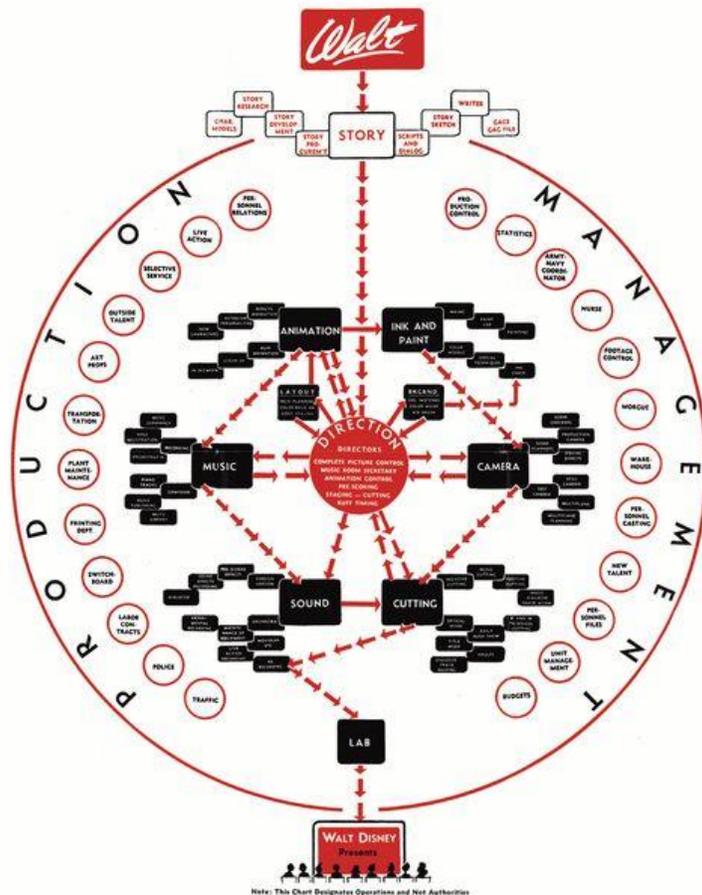
Ideally there would be a single recognition committee for all entities.

Operations define structure, not vice-versa.

Sound structures can allow exceptions.

Too many exceptions undermine structure.

## Other Organizational Structures



## Next Steps

Make recommendations for recognition.

Grant recognitions for first class of NGABs.

Develop appeals SOP.

Make recommendation for re-organization of TNI recognition activities.

Establish/facilitate communication between TNRC, NELAP AC and NEFAP.

Create web page for NGABs.

Questions?

Suggestions?