

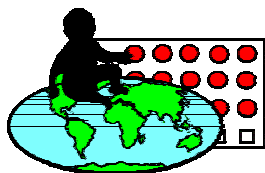
# Introduction:

## Two Projects Focused on Follow-up in Newborn Screening

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Newborn Screening Quality  
Assurance Program



# **Two Programs for Enhanced Quality in NBS**

**Clinical and Laboratory  
Standards Institute**

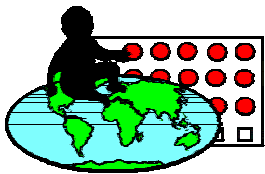
**Guideline LA-27P:  
NBS Follow-up and its QA**

**Judith Tuerck, R.N., M.S.  
Assistant Professor  
Oregon Health and Science University**

**National Newborn Screening and  
Genetic Resource Center**

**Program Evaluation and  
Assessment System  
(PEAS) for NBS**

**Bradford Therrell, Ph.D.  
Professor  
University of Texas - San Antonio**



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Assurance Program**



CLSI is an accredited developer of global voluntary consensus standards and guidelines.

- American National Standards Institute (ANSI)
- International Organization for Standardization (ISO) standards



*(Formerly NCCLS)  
Providing NCCLS standards and guidelines,  
ISO/TC 212 standards, and ISO/TC 76 standards*

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The Clinical and Laboratory Standards Institute  
mission is to enhance the value of  
medical testing and healthcare services  
through the development of consensus  
standards, guidelines, and best practices.



*(Formerly NCCLS)  
Providing NCCLS standards and guidelines,  
ISO/TC 212 standards, and ISO/TC 76 standards*

- 
- 78 Industry Organizations  
*(20 w/ Gross Sales > US \$50 Million)*
  - 2 Trade Organizations
  - 29 Professional Societies
  - 22 Government Agencies



(Formerly NCCLS)  
Providing NCCLS standards and guidelines,  
ISO/TC 212 standards, and ISO/TC 76 standards

- 
- 1,733 Hospitals and Laboratories
  - 150 Healthcare Delivery Systems
  - 45 Educational Institutions



*(Formerly NCCLS)  
Providing NCCLS standards and guidelines,  
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- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- General Laboratory Practices
- Healthcare Services
- Hematology
- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing



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A **consensus standard** or **guideline** is a document developed through the consensus process to promote uniform products, materials, methods, or practices.

A **standard** must be followed as written.

A **guideline** may be modified by the user.

### Levels of the consensus process

- *Proposed Level*
- *Approved Level*



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- Clinical, academic, regulatory, and industry scientists all use CLSI standards, guidelines, and best practice documents.
- FDA recognizes standards for use by industry in product submissions
  - Currently 82 CLSI approved documents are recognized by FDA



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- 42 new documents published in 2004
- Examples:
  - Free Thyroid Hormones; Bone Markers; Immunoassay Systems; Fluorescence Calibration; Maternal Serum Screening; Evaluation of Precision; Limits of Detection; Media Quality Control; Point-of-Care Hemostasis Testing



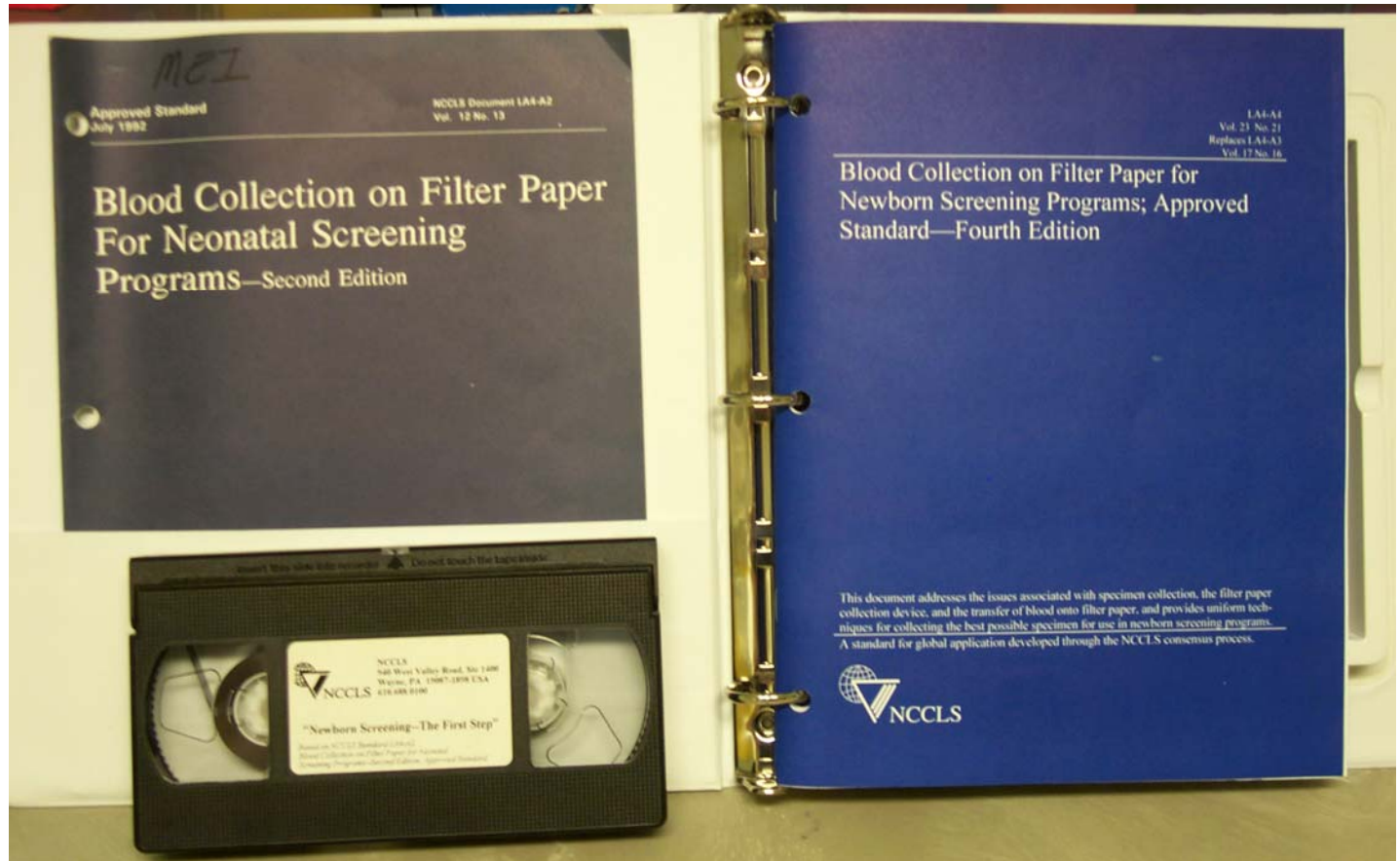
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- Blood Collection on Filter Paper for Newborn Screening Programs

Proposed Standard	1982
Approved Standard	1988
2nd ed	1992
3th ed	1997
4th ed	2003
2nd Printing	2003

# The FREDDIE Awards

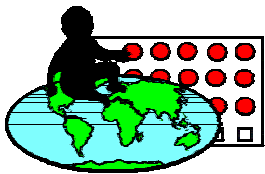
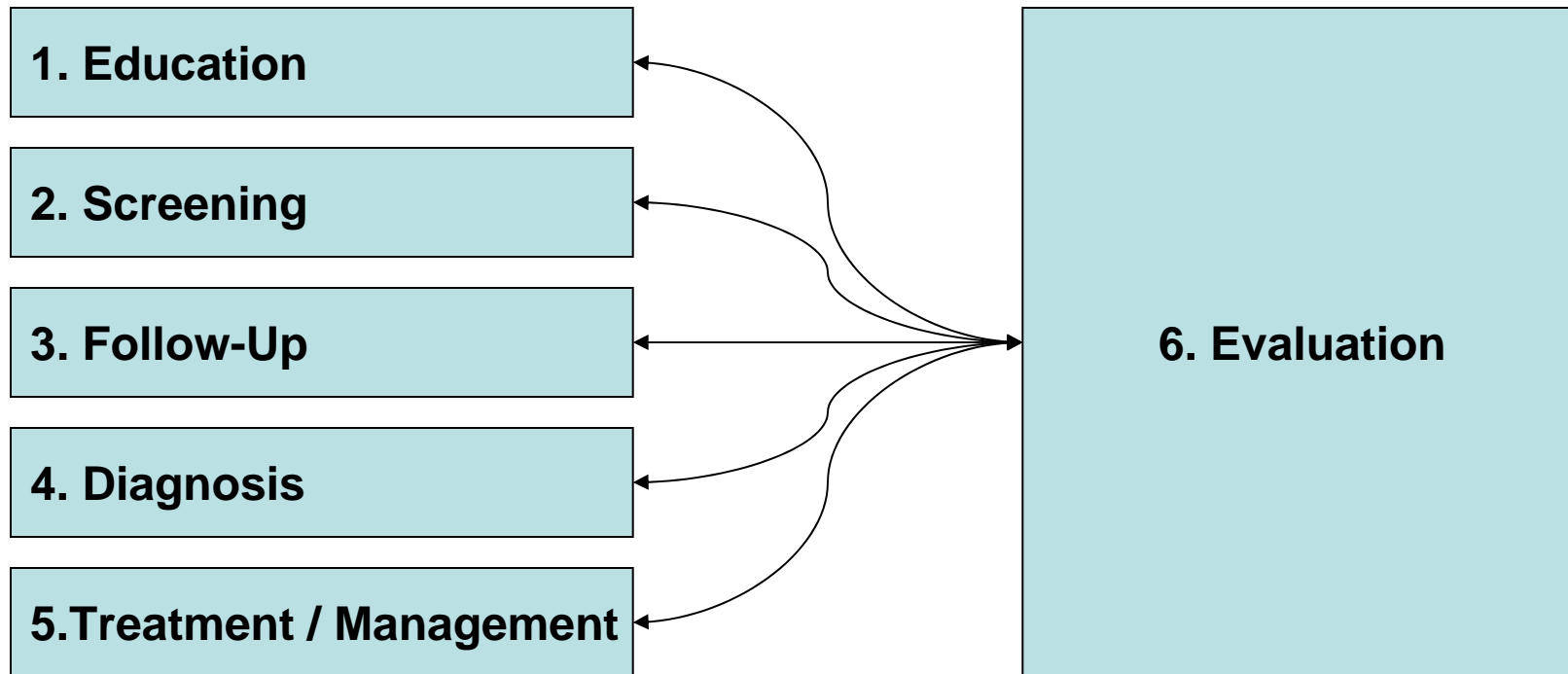
International Health & Medical Media Awards



**CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE** <sup>TM</sup>

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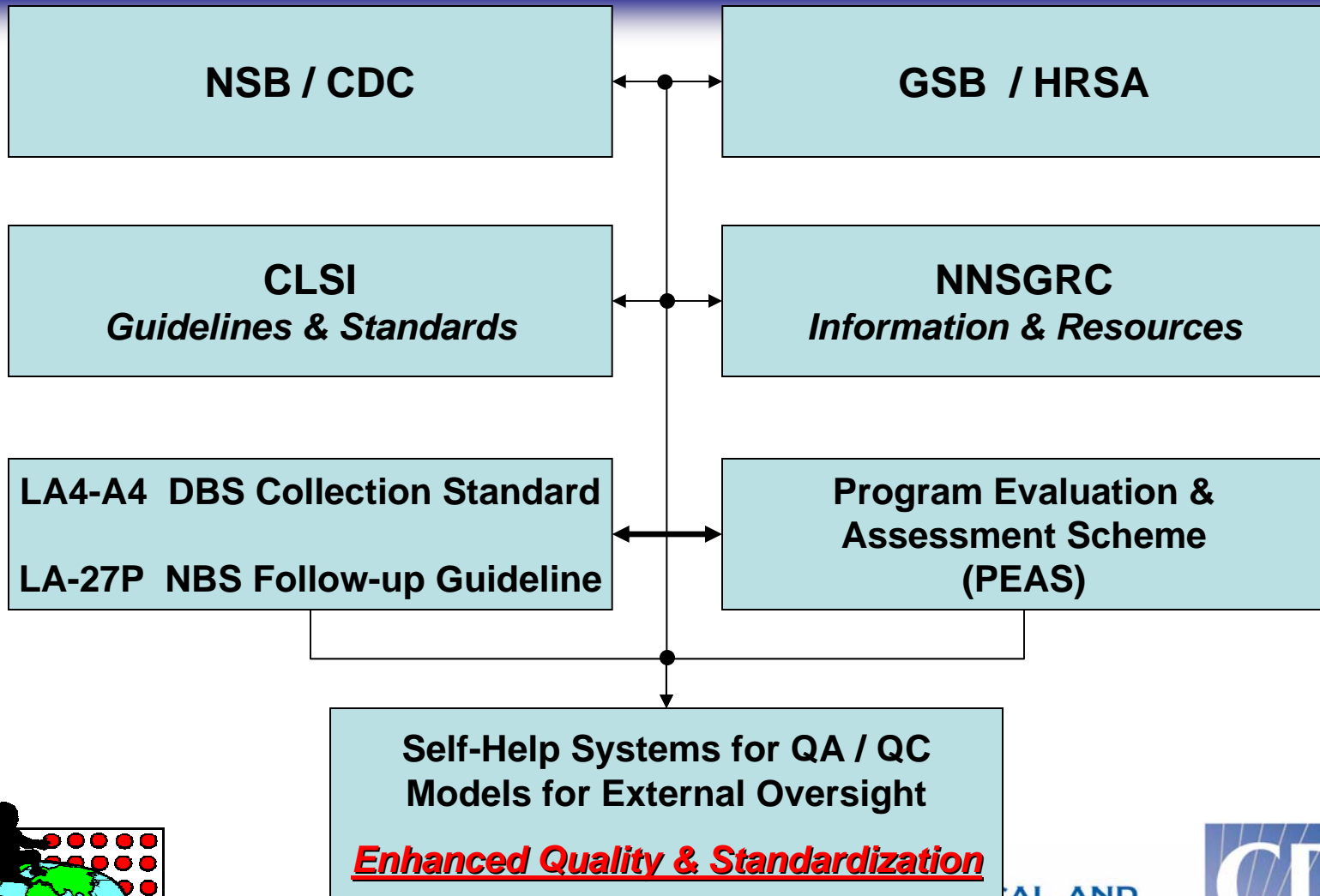
## Six Components of the Newborn Screening System



Newborn Screening Quality Assurance Program



# Two Programs for Enhanced Quality in NBS



Newborn Screening Quality Assurance Program

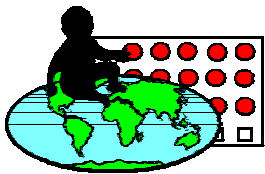


## Goals of CLSI Guideline I/LA27P:

### "Newborn Screening Follow-up Activities and its Quality Assurance"

**"The primary goal of this guideline is to improve and ensure the quality and effectiveness of short-term and long-term follow-up on newborn screened-positive results to the point of resolution."**

**"This guideline is intended to be used in both private and state-operated\* newborn screening programs by those who are involved in any aspect of newborn screening follow-up ... "**



Newborn Screening Quality Assurance Program

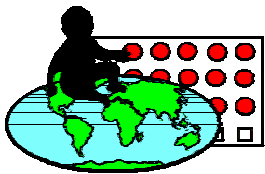
**\*NSQAP provides services to about 400 laboratories in 53 countries**



## Goals of the PEAS Project

**"... to create model PEAS for various NBS system components .... and combine them into an NBS system-wide PEAS."**

**The model PEAS will be embedded into an interactive Web site for widespread program use as a self-help tool.**



Newborn Screening Quality  
Assurance Program





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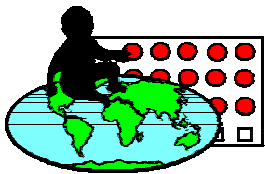
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