



SRL Accreditation: What is needed?

Dr John Ridderhof (CDC)
Chair, Global Laboratory Initiative WG
April 14, 2010
Geneva, Switzerland

Background: Challenges to SRLN

- Lack of recognition and value by funding authorities is a challenge to consistent and sufficient support for SRL activities
- SRLN focus is DST, but often country NRLs need TA for culture, general laboratory practice, network management, and microscopy EQA (“SRL Plus”)
- Currently DST performance is only criteria to become SRL. Once an SRL, few/none lose SRL status.

Why is a Laboratory Quality Management System/Accreditation Important ?

- **Assure reliability and accuracy of all tests – enhances credibility and value of laboratory**
- **Facilitates and documents laboratories' ability to meet International Health Regulation (IHR) requirements**
- **Applicable to all services**
- **Staff morale/enrichment**
- **Certification or accreditation valued by organizations and health programs purchasing services and “funding” laboratories**

How could SRLs be Accredited?

- DST performance requirements **and** ISO or country level regulations/accreditation to assure quality of overall laboratory testing
 - » **and/or**
- Special SRL accreditation program that includes DST and additional performance requirements. Would require onsite assessment of compliance (similar to Polio network)

What is sufficient country laboratory regulation?

Structured standards and objective onsite assessment

- **Personnel**
- **Test method validation / verification**
- **Quality control**
- **Quality assurance**
- **Equipment calibration and maintenance**
- **External quality assessment and proficiency testing**
- **Documents management (includes SOPs)**
- **Information management**
- **Safety and facilities**

Polio WHO Accreditation

- **Accreditation provides documentation that a laboratory performing intratypic differentiation (ITD) of polio viruses (ITD laboratory) has the capability and the capacity to detect and identify the serotype and intratype of polioviruses that may be present in any specimen...and refer such isolatesfor genetic characterization.**
- **Accreditation based on eight criteria for performance that include EQA performance, turnaround for reporting and referring, and onsite evaluation of procedures and practices**
- **Test results are accepted only from a WHO accredited Poliovirus Laboratory**

Implement SRL service requirements?

- SRL service requirements:
 - Minimum level of strains retested per year?
 - Minimum of NRLs/countries supported?
 - Minimum technical assistance visits?

Challenges

- What country regulation is sufficient?
- Accreditation programs are expensive and require clear consensus standards and trained auditors
- Can current SRLs meet accreditation standards?
- Is a provisional status required to recognize temporary fluxuations in service and signal need to improve?