National Polio Laboratory
Check List for Annual WHO Accreditation

Introduction

Surveillance of acute flaccid paralysis (AFP) at an annual non-polio rate of ≥1/100,000 in children less than 15 years is the standard for certifying polio eradication for all countries. The ultimate goal is a poliomyelitis classification system based on virologic evaluation of all AFP cases. Virologic evaluation consists of tests on two adequate stool specimens collected 24-48 hours apart from each AFP patient within 14 days of onset of paralysis. Supplemental virus surveillance may be required where appropriate, including specimens from special surveys of healthy children, contacts of AFP cases, and the environment. For certification purposes laboratory results are accepted only from a WHO accredited poliovirus laboratory.

Accreditation provides documentation that the laboratory has the capability and the capacity to detect, identify, and promptly report wild polioviruses and vaccine derived polioviruses (VDPV) that may be present in clinical and environmental specimens. The accreditation process further provides a learning opportunity, a mechanism for identifying resource and training needs, a measure of progress, and a link to the Global WHO Laboratory Network.

Accreditation of National Poliovirus Laboratories is reviewed annually by the WHO Regional Office and is based on laboratory performance during the immediately preceding 12 months with complete data, usually from 13 months to 1 month prior to evaluation. Accreditation is given for the upcoming calendar year.

Seven criteria for accreditation:

1. **Test results are reported by the laboratory on at least 80% of AFP specimens within 28 days of receipt.**
   This criterion may be met for all virus negative specimens after 2 passages in 14 days. Similarly, viruses that demonstrate cytopathic effect (cpe) within the first week of incubation may be identified within the 28-day time frame. Viruses that appear late in passage, virus mixtures, or viruses that present typing difficulties may require longer than 28 days.

2. **Virologic tests are performed on at least 150 stool specimens annually.**
   Fully active virus laboratories that maintain the appropriate cell cultures weekly and annually test 150 stool specimens of any origin for any enteric viruses are deemed to meet this criterion. Laboratories anticipating less than this number may collaborate with the EPI staff to develop protocols for sampling stools from healthy children in high risk areas, routinely testing specimens from meningitis cases, or other epidemiologically sound virus surveillance activities.

3. **The accuracy of poliovirus detection and identification among all virus isolates is at least 90%.**
   Accuracy is determined by the agreement in test results on all poliovirus isolates submitted by the National Laboratory to the Regional Reference Laboratory (RRL) during the 12-month review period.

4. **At least 80% of poliovirus isolates from AFP cases are forwarded to the RRL for ITD within 7 days of obtaining typing result.**
   It is essential that the polio eradication programme be aware of wild poliovirus and Vaccine Derived Polioviruses (VDPV) isolations as soon as possible. All poliovirus isolates from AFP cases, contacts and suspected polio cases must be forwarded without delay to the Regional Reference laboratory for intratypic differentiation. Polioviruses from non-AFP sources or supplementary surveillance activities (e.g. polioviruses from environmental samples) should also be subjected to ITD tests and should be forwarded to reference laboratories as soon as possible.

5. **Internal quality control (QC) procedures for L20B and RD cell culture sensitivity are implemented in accordance with the WHO protocol.**
   Ideally cell line sensitivity should be known for all frozen stocks and evaluated whenever fresh cells are resuscitated or received in the laboratory. It is recommended that cells are evaluated at least midway through their expected use of 15 passages. Assessing sensitivity before discarding at 15 passages can reassure the laboratory that sensitivity has been maintained throughout the period of use, but is not essential for accreditation. Original QC data sheets and summaries of corrective action are retained for documentation and discussion with reviewer.

6. **The score on the most recent WHO approved proficiency test is at least 80%.**
   Proficiency test (PT) results must be reported within 28 days of panel receipt to receive full credit.

7. **The score from the annual on-site review of laboratory operating procedures and practices is at least 80%.**
   For Laboratories with consistently high annual scores, the Regional Laboratory Coordinator may waive the on-site review upon satisfactory completion of the annual checklist by the laboratory.

   The annual non-polio enterovirus (NPEV) isolation rate from all stool specimens:
   The NPEV rate is not a criterion for accreditation because of the variability of findings influenced by a number of factors, including the season of the year, elevation, or population hygienic levels. However, the rate may be a useful indicator of laboratory performance and should be discussed with the reviewer. The annual NPEV isolation rate in most tropical countries typically exceeds 10%.

A Laboratory that achieves less than the passing score on any one of the applicable criteria will work with the Regional Laboratory Coordinator to:

- Identify areas where improvement is needed.
- Develop and implement a work plan.
- Monitor laboratory progress.
- Provide for re-testing where required.
- Continue steps to achieve full accreditation.

A Laboratory that fails to achieve a passing PT test score within 6 months after annual review is deemed non-accredited and arrangements must be made for an accredited Laboratory to perform duplicate tests on all specimens.

This checklist is designed primarily for Laboratories in countries that perform AFP surveillance. Applicable components of criteria 2-7 may be used for Laboratories in other public health-related activities.

The checklist consists of four parts. **Part I** summarizes the findings of the review and the data on which accreditation is based. **Part II** provides a worksheet to calculate and record laboratory performance for **criteria #1** through **#6** for the immediately preceding 12 months where data are complete. (Selection of the most recent 12-month period, rather than the most recent calendar year as a basis for calculation, provides an assessment of current performance and permits review of laboratories at any time during the calendar year.) **Part III** provides a profile of the laboratory and serves to identify resource needs. **Part IV** is a checklist for evaluation of laboratory operating procedures and practices for **criterion #7**.

This checklist does not include all laboratory activities or all situations. It is intended to serve as a guide. The experienced reviewer is expected to ask detailed questions and make additional suggestions as appropriate to assure high quality laboratory performance.

National Polio Laboratory
Check List for Annual WHO Accreditation

Laboratories are to be notified in advance of the accreditation review and provided a copy of this form to assist in gathering information.

Dates of Review:	Accreditation for Calendar Year:	
Laboratory:		
Address:		
Phone:	Fax:	E-mail:
Head of Department:		
Head of Laboratory:		
Technical Supervisor:		
Reviewers:		
Name of National Accrediting Authority and current accreditation status:		

Part I: Summary of Review

Recommendations (check one):

- ☐ Accredit: Laboratory meets all criteria
- ☐ Provisionally accredit: Laboratory passed the most recent proficiency test, but failed to achieve one or more of the remaining criteria
- ☐ Do not accredit: Laboratory did not pass the most recent proficiency test

Findings:

1.	Test results on at least 80% of all AFP specimens are reported within 28 days:	**%**
2.	Tests are performed on at least 150 stool specimens annually:	
3.	Accuracy of poliovirus typing is at least 90%:	**%**
4.	At least 80% of AFP poliovirus isolates are forwarded for ITD within 7 days:	**%**
5.	Internal quality control procedures for cell cultures are implemented:	
6.	Result on most recent isolation PT is at least 80%:	**%**
7.	Score on annual on-site review is at least 80%:	**%**

Annual NPEV isolation rate is:	**%**

SUMMARY, COMMENTS AND RECOMMENDATIONS:

Part II: Laboratory Performance in Previous 12 Months

Dates from: / / to / /
d m y *d m y*

1.	**Percentage of AFP Test Results Reported within 28 Days:**	**%**
1.1	Number of stool specimens from AFP cases tested:	
1.2	Number with isolation and identification test results reported within 28 days:	

COMMENTS AND RECOMMENDATIONS:

2.	**Total Number of Specimens Tested from all sources:**	
2.1	Stool specimens tested for Polio:	
	AFP (same as 1.1 above):	
	Contacts:	
	Special surveys:	
2.2	Other specimens tested for polio:	
	Environmental:	
	Vaccine potency assays:	
	Other specimens (e.g. CSF, throat swabs etc.):	
2.3	Specimens tested in cell culture for all other viruses:	

COMMENTS AND RECOMMENDATIONS:

3.	**Percent Poliovirus Isolates with Identification Confirmed By RRL:**	**%**
3.1	Number of polioviruses isolated:	
3.2	Number forwarded to RRL:	
3.3	Number confirmed by RRL:	

COMMENTS AND RECOMMENDATIONS:

4.	**Percent poliovirus isolates from AFP cases forwarded to RRL for ITD within 7 days of obtaining typing result:**	**%**

COMMENTS AND RECOMMENDATIONS:

5.	**Routine Internal Quality Control Procedures Implemented:**	

DESCRIBE RESULTS AND ACTION TAKEN:

6.	**Result of Most Recent Poliovirus isolation and identification Proficiency Test:**			**%**
6.1	Date of panel receipt:	/	/	
6.2	Date of test report:	/	/	

COMMENTS AND RECOMMENDATIONS:

Non-polio Enterovirus (NPEV) isolation rate from stools:	**%**
Total number of NPEV isolates:	
Total number of stools tested:	

COMMENTS AND RECOMMENDATIONS:

Part III: Laboratory Profile

1.	**Staff**
1.1.	Number of scientific and technical staff assigned to poliovirus laboratory: Please list according to function, indicating years of polio laboratory experience and proportion of current working time spent on polio-related activities.

Names of staff	Position Title or Duties	Full-time or Part-time	% of time spent working on polio	Years of experience in Polio Lab

COMMENTS AND RECOMMENDATIONS:

2.	**Space** (provide floor plan or sketch of laboratories if possible)	
2.1.	Total m^2 available:	
2.2.	Number of rooms:	
2.3.	Separate cell culture room:	

COMMENTS AND RECOMMENDATIONS:

Part IV: Laboratory Operating Procedures and Work Practices

1.	Space (4%)	Score:	
1.1.	Space is used efficiently with appropriate equipment placement:		
1.2.	Space configuration is adequate and consistent with good laboratory practices:		
1.3.	Space is clean and well kept		

COMMENTS AND RECOMMENDATIONS:

2.	Staff (4%)	Score:	
2.1.	Staff are effectively assigned:		
2.2.	The number of trained staff are adequate to handle the workload:		

COMMENTS AND RECOMMENDATIONS:

3.	Supervision (4%)	Score:	
3.1.	The lines of supervision and accountability are clear:		
3.2.	Supervisor critically reviews test results:		

COMMENTS AND RECOMMENDATIONS:

4.	Cell Lines (14%)	Score:	
4.1.	Appropriate written protocols are available for:		
	a. Freezing and recovery of cells:		
	b. Routine passage of cells:		
4.2.	RD and L20B are in use:		
4.3.	Both cells are available for inoculation weekly:		
4.4.	Cells are obtained from approved WHO stocks:		
4.5.	Low passage stocks are stored in liquid nitrogen:		
4.6.	Cells are routinely replaced at least after 3 months or 15 passages:		
4.7.	Monolayers remain healthy for at least 5 days:		
4.8.	Cells are passaged and maintained in space separate from that used for specimen processing and virus inoculation:		
4.9.	Media and cells are prepared at separate times:		
4.10.	Permanent records are maintained on cell passage and storage histories:		
4.11.	Reagents and stock solutions are labeled correctly (including dates of preparation and expiration), sterility tested and stored at indicated temperatures:		

COMMENTS AND RECOMMENDATIONS:

5.	Stool Specimens (14%)	Score:	
5.1.	Appropriate written protocol for processing specimens is available:		
5.2.	Specimens are processed by chloroform extraction in accord with WHO protocols:		
5.3.	Extracts are stored at –20°C if not inoculated on same day as processed:		
5.4.	All potentially infected clinical materials are processed in a biological safety cabinet:		
5.5.	Original specimens (in original containers) are appropriately labeled and stored at –20°C for at least 12 months:		
5.6.	Stool extracts are discarded within 3 months of confirmation of result:		
5.7.	Specimens, extracts, all virus isolates, and other potentially infectious materials are stored separately from non-infectious materials in designated freezers and refrigerators:		

COMMENTS AND RECOMMENDATIONS:

6.	Virus Isolation (14%)	Score:	
6.1.	Appropriate written protocols are available:		
6.2.	Extracts are inoculated within 7 days of processing:		
6.3.	Extracts are inoculated on duplicate RD and L20B cell cultures at the same time:		
6.4.	RD(+)/L20B(-) isolates are passed into L20B cells:		
6.5.	Aerosol resistant tips (ART) with micropipettors, or, cotton plugged sterile pipettes, are used for inoculation and manipulation of cell cultures		
6.6.	The first and second specimens from each patient are processed and inoculated separately, never combined:		
6.7.	Records are maintained on daily observations of inoculated cells:		
6.8.	Two sequential passages of 7-10 days are performed in RD and L20B cell lines before recording as negative (minimum time in culture is 14 days total):		

COMMENTS AND RECOMMENDATIONS:

7.	Virus Identification (14%)	Score:	
7.1.	Appropriate written protocols are available:		
7.2.	WHO approved poliovirus typing sera are used:		
7.3.	WHO typing sera are diluted as recommended, labeled appropriately, and stored in aliquots at –20°C:		
7.4.	Other typing sera, if used, are documented to be equivalent in specificity and sensitivity to WHO sera:		
7.5.	Virus typing worksheets are retained as permanent records:		
7.6.	Isolates are stored at –20°C or lower for at least 12 months:		
7.7.	Storage vials are clearly and permanently labeled:		
7.8.	Permanent records are maintained on the identity and location of all isolates:		

COMMENTS AND RECOMMENDATIONS:

8.	**Biosafety and containment of polioviruses (8%)**	**Score:**	
8.1.	Employees have been instructed in biosafety:		
8.2.	Written instructions are available to all employees:		
8.3.	Biosafety practices are enforced, including:		
	a. Hand washing:		
	b. Pipetting with aid of mechanical device:		
	c. Routine use of gloves and lab coats		
	d. No eating, drinking, smoking, or storage of food in laboratory		
	e. Decontaminating all infectious or clinical waste before discarding:		
	f. Decontaminating lab work surfaces:		
	g. Immunizing staff against polio:		
8.4.	Biosafety cabinets and clean air cabinets are used for potentially infected and clean materials, respectively:		
8.5.	Safety cabinets are maintained as recommended, including filter changes, and dates recorded:		
8.6.	A written inventory is available of all stored poliovirus isolates and materials that potentially contain polioviruses		
8.7.	Poliovirus isolates and potentially infected materials are stored at < -20^{0}C, in locked freezers and/or in laboratories with limited (locked) access		

COMMENTS AND RECOMMENDATIONS:

9.	**Equipment (4%)**	**Score:**	
9.1.	Equipment is functioning and in good condition:		
9.2.	Equipment is maintained periodically as recommended and dates recorded:		
9.3.	Equipment location is conducive to optimal performance:		
9.4.	Records are kept on daily temperature readings of incubators, refrigerators, and freezers:		

COMMENTS AND RECOMMENDATIONS:

10.	**Supplies (4%)**	**Score:**	
10.1.	Current inventories are maintained:		
10.2.	Adequate time is allowed for replenishing supplies:		

COMMENTS AND RECOMMENDATIONS:

11. Cooperation with EPI Staff (8%)	**Score:**
11.1. Lab and EPI staff communicate/meet at least monthly:	
11.2. EPI staff are contacted if specimens arrive without adequate information or EPID numbers:	
11.3. Lab staff member(s) serve on:	
a. AFP review committees:	
b. NID planning committees:	

COMMENTS AND RECOMMENDATIONS:

	Virus isolation data base (8%)	Score:
12.1	Laboratory reports are submitted to the WHO regional office with the agreed frequency and format	
12.2	The following data are available on all polio and non-polio enterovirus isolates:	

Variable description	Virus Isolation Lab		Intratypic Differentiation Lab	
	Needed	Available	Needed	Available
Epidemiology and case identification				
EPID no.	✔		✔	
Specimen no. from virus isolation lab	✔		✔	
Specimen no. from intratypic differentiation lab			✔	
Name of patient	✔		✔	
District/municipality code of patient	✔		✔	
Province/state code of patient	✔		✔	
Country code of patient	✔		✔	
Date of last OPV	✔			
Specimen number (i.e. 1st or 2nd)	✔		✔	
Specimen source	✔			
Date of paralysis onset	✔		✔	
Date of specimen collection	✔			
Lab doing virus isolation			✔	
Virus isolation				
Condition of stool upon arrival	✔			
Date stool inoculated	✔			
P1 isolated	✔			
P2 isolated	✔			
P3 isolated	✔			
Non-polio enterovirus isolated	✔			
Poliovirus(es) isolated but type(s) unknown	✔		✔	
Date typing results available	✔			
Date typing results reported to EPI	✔			
Intratypic differentiation				
Date isolate inoculated			✔	
Date isolate sent for intratypic differentiation	✔*			
Date isolate received in lab for intratypic differentiation			✔*	
Name of intratypic differentiation lab	✔*			
P1 intratypic differentiation	✔		✔	
P2 intratypic differentiation	✔		✔	
P3 intratypic differentiation	✔		✔	
Date intratypic differentiation results available	✔		✔	
Date intratypic differentiation reported to EPI			✔	
Sequencing information				
Poliovirus isolate sent for sequencing			✔	
Date poliovirus referred for sequencing			✔	
Name of sequencing laboratory			✔	

Total Score:	

*Not applicable if virus isolation and intratypic differentiation performed in same lab