WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

REVIEW OF POLIOMYELITIS LABORATORY ACTIVITIES
IN CHINA

13-23 October 1997
Report of the International Review Team Members

Manila, Philippines
May 1998
REVIEW OF POLIOMYELITIS LABORATORY ACTIVITIES IN CHINA

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Not for sale

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May 1998
NOTE

The views expressed in this report are those of the international members of the team reviewing the poliomyelitis laboratory activities in China and do not necessarily reflect the policies of the World Health Organization.

This report has been printed by the Regional Office for the Western Pacific of the World Health Organization for the international members of the team which reviewed the poliomyelitis laboratory activities in China from 13 to 23 October 1997.
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Poliomyelitis - prevention and control / Laboratories / China
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EXECUTIVE SUMMARY

No indigenous wild polioviruses have been detected in the People's Republic of China since 1994, and it appears that indigenous wild poliovirus transmission in China has been interrupted. For the WHO Western Pacific Region as a whole, available information suggests that 1997 will probably be the year in which the last indigenous wild polioviruses in the Region are detected. If this is the case, certification of poliovirus eradication in this Region can take place at the end of 2000, or early in 2001. The elimination of wild polioviruses can only be confirmed, however, if there is an excellent poliovirus surveillance system in place. The poliomyelitis laboratory network plays a critical role in this surveillance system. To investigate the conditions and performance of the poliomyelitis laboratory network in China, teams of national and international laboratory experts carried out a review of 25 provincial poliomyelitis laboratories from 13 to 23 October 1997. A WHO check list for accreditation of National Poliomyelitis Laboratories was used by each team to assess the performance of all laboratories with reference to WHO-recommended performance criteria.

Despite the increased workload in the past three years there have been major improvements in laboratory performance, with many laboratories now reaching the routine performance goals set by WHO. A high level of technical proficiency was found in almost all of the laboratories reviewed. Many of the outstanding equipment requirements have been met or are being met, largely through the support of Rotary International and Japan International Cooperation Agency. Most of the problems that existed two years ago have now been solved. There remain some problems with ensuring continued supply of essential reagents and supplies to all laboratories, but these problems are now being addressed, and will be resolved.

Limitations on the performance of the poliomyelitis laboratories are now largely restricted to operational issues. These issues can be addressed through appropriate training and retraining of laboratory staff, and by ensuring that all poliomyelitis laboratories have the full support of provincial governments and public health authorities.

All laboratories are now performing well in the annual proficiency tests, but these tests fail to monitor routine laboratory performance. A routine quality assurance system now needs to be established, retesting a proportion of NPEV isolates and negative stool specimens from each laboratory. This task cannot be expected to be carried out by the National Laboratory alone, and an additional level of laboratories should be established, under the direction of the National Laboratory, to carry out the quality assurance programme and to coordinate the network.

Coordination and evaluation of the surveillance system now depend on the rapid exchange of accurate information between laboratory and acute flaccid paralysis (AFP) surveillance staff, and between provincial and national levels. Communications between laboratory and AFP are now good in many provinces, but laboratory results must be actively reviewed by laboratory and Expanded Programme on Immunization (EPI) staff on a regular basis. Laboratory staff do not check the database for entry errors, and do not ensure that the database is updated when new information or results become available. This situation must be improved before certification of poliovirus eradication can be adequately documented.
Major recommendations include the following:

(1) Laboratories that have been reviewed and found to meet the accreditation requirements of WHO should be regarded as accredited laboratories for the next 12 months. The performance of these laboratories should be reviewed after 12 months.

(2) Laboratories that have been reviewed and found to meet the accreditation requirements of WHO but were found to have some problems with laboratory procedures should be regarded as accredited laboratories for the next six months. Recommendations and support should be given to improve laboratory performance and the review repeated after six months.

(3) Laboratories that have been reviewed and found not to meet the accreditation requirements of WHO should be given recommendations, training, and support to improve laboratory performance. The review should be repeated after 6 months or 12 months, as appropriate.

(4) In order to strengthen the laboratory network in China, some of the best provincial laboratories should be promoted to sub-national laboratories and take responsibility for checking the performance of laboratories of neighbouring provinces.

(5) To improve biosafety awareness and practice relevant sections of the WHO Laboratory Biosafety Manual should be translated into Chinese and distributed to all laboratories.

(6) Supply and distribution of laboratory supplies and equipment by WHO and some other international agencies has been only partly successful, and WHO, the Ministry of Health and the Chinese Academy of Preventive Medicine (CAPM) must, as a matter of urgency, develop a system for monitoring equipment ordering, distribution, installation and maintenance.

(7) In-service and refresher training requirements for laboratory staff in laboratory procedures, laboratory management and computer data management should be reviewed and a comprehensive plan for providing appropriate training developed and implemented.

(8) The routine collection and processing of stool samples from contacts of AFP cases should be stopped. Contact stool specimens should only be collected if:
   - the provincial laboratory does not expect to receive at least 150 specimens each year from AFP cases;
   - adequate stool specimens were not collected from the AFP case within two weeks of onset of paralysis;
   - the AFP case died or is strongly suspected to be poliomyelitis on the basis of clinical presentation or epidemiological information.
I. INTRODUCTION

China has made very impressive progress towards the elimination of poliomyelitis. The poliomyelitis laboratory network, established in 1992, now plays a crucial role in the surveillance for wild polioviruses in China. More than 4500 acute flaccid paralysis (AFP) cases, most with two stools collected, have been investigated each year since 1995, but no indigenous wild poliovirus-associated cases have been detected in the past three years. One imported wild poliovirus-associated case was detected, towards the end of 1995, and three more imported cases were found in the first quarter of 1996. Rapid detection and reporting of these cases demonstrated the sensitivity and effectiveness of the virological surveillance system in China.

Improvements during the past two years have seen laboratories reach most of the performance criteria goals established by WHO. As the poliomyelitis eradication programme in China moves towards its final stages, laboratory information plays an increasingly important role. It is now essential that laboratories produce accurate results in a timely manner, and that these results, and the documentation that supports them, are available for action and analysis.

Support from Japan International Cooperation Agency (JICA), Rotary International, UNICEF, United States Centers for Disease Control and Prevention (CDC), and WHO has been important in helping China establish and develop its poliomyelitis laboratory network, and to reach its current level of achievement. Continued international support will now be necessary to help China continue to develop its poliomyelitis laboratory network and to achieve certification of poliomyelitis eradication in a timely manner.

Following a successful review of 12 poliomyelitis laboratories in selected provinces of China from 14 to 21 October 1996, the Ministry of Health conducted a review of 25 provincial poliomyelitis laboratories from 13 to 23 October 1997. The review was carried out with the participation of the Chinese Academy of Preventive Medicine (CAPM), JICA, Centers for Disease Control and Prevention, Atlanta, USA, National Institute of Infectious Diseases, Tokyo, Japan, Victorian Infectious Diseases Reference Laboratory, Fairfield, Australia and WHO.

Eight teams of international and national reviewers interviewed laboratory staff and collected information using a standard WHO Check List for Accreditation of National Poliomyelitis Laboratories in visits to 25 provincial poliomyelitis laboratories. The review process was chaired by Professor Zhang Libi, Head of Virology, CAPM and Dr Ray Sanders, WHO Regional Office for the Western Pacific. A presentation of the summary of findings of the review was made to the Vice-Minister of Public Health, Dr Yin Dakui, on 23 October 1997. The final report of this review follows, with observations and recommendations of team visits to 25 provincial laboratories.

1.1 Objectives

The objectives of the review were:

(1) to conduct a detailed review of selected provincial poliomyelitis laboratories with regard to current laboratory practice, laboratory support and laboratory proficiency, with particular reference to the accreditation of the laboratories within the National Poliomyelitis Eradication Programme;

(2) to make recommendations for improvements in laboratory practice and performance if required; and
(3) to assess remaining laboratory equipment and support needs of the poliomyelitis laboratory network in China, and to provide a framework of expected laboratory network costs until certification of poliomyelitis eradication is achieved.

1.2 Methods

Two-person or three-person teams, composed of international staff matched with national counterparts from the CAPM and provincial laboratories not included in this review, visited 25 provincial poliomyelitis laboratories in 2-3 day site visits. Annex 1 shows a map of China displaying the 25 provinces visited in the review. The 25 provincial laboratories were selected on the basis of not having been visited during the previous laboratory review or of having had problems identified during that review. The laboratories in Tibet and Chongqing were excluded from the review because it was not possible to arrange a trip to Tibet, and the laboratory in Chongqing is not yet fully established. Annex 2 contains a complete list of the review team members and provinces visited. Detailed discussions were held with laboratory staff on aspects of technical proficiency; laboratory facilities and laboratory records were examined. The standard Check List for Annual WHO Accreditation of National Poliovirus Laboratories, developed by WHO, was used to facilitate the review process. Annex 3 contains a copy of the Check List used in the review, and Annex 4 shows a summary table of review findings and proposed actions. At the end of each visit oral reports and recommendations were made to senior staff in provincial health bureaus and epidemic prevention stations. Annex 5 includes summary findings and recommendations made by the review teams on each of the laboratories visited.

1.3 Provincial poliomyelitis laboratories visited

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<td>25 Jiangsu</td>
<td>Nanjing</td>
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2. BACKGROUND

2.1 Findings from the 1996 review

A review of 12 poliomyelitis laboratories in selected provinces of China was carried out from 14 to 21 October 1996. It was found that despite the increased workload there had been major improvements in laboratory performance, with many laboratories reaching the performance goals set by WHO. A high level of technical proficiency was found in each of the laboratories reviewed. Many of the outstanding equipment requirements had been met or were being met, largely through the support of Rotary International and JICA. There remained some problems with ensuring continued supply of essential reagents and supplies to all laboratories, but these problems were being addressed.

Limitations on the performance of the poliomyelitis laboratories were largely restricted to operational issues. It was felt that these issues could be addressed through appropriate training and retraining of laboratory staff, and by ensuring that all poliomyelitis laboratories had the full support of provincial governments and public health authorities.

The only area that required significant improvement was the coordination of laboratory activities with AFP surveillance activities. Coordination and evaluation of the surveillance system depends on the rapid exchange of accurate information between laboratory and AFP surveillance staff, and between provincial and national levels. Communications between laboratory and AFP staff needed to be improved in many provinces.

Significant discrepancies were noted between the records of virus isolation and characterization held in the laboratory and those which appeared in the provincial laboratory databases sent to CAPM. Laboratory staff were not checking the database for entry errors, and did not ensure that the database was updated when new information or results became available.

Of the 12 laboratories reviewed in 1996, four were found to be of a standard that would be acceptable for WHO accreditation of poliomyelitis laboratories. These laboratories were in Guangxi, Zhejiang, Hubei, and Neimongol. Recommendations were made to improve the performance of the other eight laboratories visited.

A major recommendation from the review was that a mechanism should be established to ensure that all provincial laboratories have a reliable supply of good quality antisera for typing of isolates. In response WHO Regional Office for the Western Pacific has undertaken to supply all provincial laboratories with RIVM panels of poliovirus typing sera, and has been distributing kits through the Regional Reference Laboratory in Beijing.

Another recommendation was that all laboratories should have high quality fetal bovine serum or newborn calf serum available for tissue culture use. During the past year the Regional Reference Laboratory has initiated a system for batch-testing locally produced newborn calf serum for distribution to provincial poliomyelitis laboratories. This supply has been supplemented by internationally procured fetal bovine serum supplied by the WHO Regional Office and distributed through the Regional Reference Laboratory.
3. GENERAL FINDINGS

3.1 Laboratory practice and performance

3.1.1 Findings

The poliomyelitis laboratory network in China is now well established and is working very effectively. Each year, for the past three years, more than 20,000 stool specimens from AFP cases and contacts have been collected, transported, processed and the results recorded and reported. All laboratories visited in this review were following standard, recommended laboratory procedures for the isolation and characterization of polioviruses. Almost all laboratories had prepared their own standard operating procedures, based on WHO-recommended procedures and promoted by the National Poliomyelitis Laboratory. Routine laboratory performance has continued to improve over the past two years, so that most laboratories have now reached the WHO standard for laboratory accreditation.

For China as a whole, more than 90% of AFP cases have laboratory results provided within 28 days of receipt of the stool specimens in the laboratory. The isolation rate for non-polio enteroviruses (NPEV) for the past 12 months was above 12% for the country as a whole, with some laboratories in the southern part of the country achieving a rate of above 20%. For many of the laboratories with annual NPEV isolation rates less than 10%, analysis of seasonal variation revealed that isolation rates in the warm summer months was often above 15%, but that rates in the cold winter months were less than 5%. On this basis, low annual NPEV isolation rates, but high rates during the peak enterovirus transmission season, could be reconciled with WHO accreditation requirements.

The annual workload in many laboratories has now been set at a very high level. In several laboratories the workload is maintained at an unnecessarily high level by the continued processing of specimens from contacts of AFP cases. It is now generally accepted that there are no programmatic advantages to be gained from routine collection and processing of stool specimens from contacts of every AFP case. It is possible that continued processing of stool specimens from contacts of AFP cases, even when stools from multiple contacts of the same case are pooled, is having an adverse effect on the quality of laboratory performance when processing specimens from AFP cases.

The provincial poliomyelitis laboratories have also maintained an excellent record with respect to the annual proficiency test scores. In 1996 only one of the 30 laboratories tested failed to achieve a passing score. In 1997 all 30 laboratories achieved a proficiency test score of 100%. Annual proficiency testing, however, is not a reliable indicator of routine sensitivity and accuracy. Concerns have been raised over the possibility that some laboratories are failing to detect polioviruses in stool specimens, or are incorrectly typing virus isolates. The National Laboratory has attempted to develop some small-scale quality control programmes to monitor routine proficiency, and has detected problems in some laboratories. A comprehensive quality control system, retesting a portion of all NPEV isolates and negative stool specimens from each laboratory is now required. The additional workload of such a system cannot be placed upon the National Laboratory. It is now time to develop an additional tier of laboratories in China, below the level of the National Laboratory, but above the level of the majority of provincial laboratories. These sub-national laboratories, which should number no more than 3 or 4, would support the National Laboratory in maintaining a quality control system and in coordinating the laboratory network.
A low level of biosafety awareness was found in several laboratories. Although basic precautions against accidental infection of laboratory staff were in place in most laboratories, methods for disinfecting benches and cabinets and for safe disposal of infectious materials were not always adequate. Not all laboratories used biohazard safety cabinets for the handling of infectious materials.

Although the general level and standard of laboratory record keeping was high, none of the laboratories visited maintained daily records of incubator, refrigerator and freezer temperature readings. Similarly, none of the laboratories maintained functional inventories of laboratory supplies and reagents. Laboratories have not previously been told to maintain these records, and therefore could not be penalized for failing to do so. All laboratories visited were advised to maintain these records.

Staff turnover in many of the laboratories remains high. Older, more experienced laboratory staff are being promoted to higher positions, or retiring. Younger staff members are moving to other fields once they have received basic laboratory training. This results in a persistent requirement for staff training and retraining. Although training requirements have been met by the National Laboratory, there is a requirement for a more systematic and extensive training programme for laboratory staff at various levels.

3.1.2 Recommendations

(1) The routine collection and processing of stool samples from contacts of AFP cases should be stopped. Contact stool specimens should only be collected if:

- the provincial laboratory does not expect to receive at least 150 specimens each year from AFP cases;
- adequate stool specimens were not collected from the AFP case within two weeks of onset of paralysis;
- the AFP case died or is strongly suspected to be poliomyelitis on the basis of clinical presentation or epidemiological information.

(2) In order to strengthen the laboratory network in China, some of the best provincial laboratories should be promoted to sub-national laboratories and, under the direction of the National Laboratory, help to coordinate the network and participate in a routine quality control system.

(3) To improve biosafety awareness and practice, relevant sections of the WHO Laboratory Biosafety Manual should be translated into Chinese and distributed to all laboratories.

(4) Clear instructions on standard methods of laboratory stock and daily record keeping, including the recording of daily temperature monitoring of all refrigerators, freezers and incubators, should be developed and issued to all laboratories.

(5) In-service and refresher training requirements for laboratory staff in laboratory procedures, laboratory management and computer data management should be reviewed and a comprehensive plan for providing appropriate training developed and implemented.
3.2 Coordination and communication of laboratory findings

3.2.2 Findings

Cooperation and coordination between laboratory and epidemiology staff has improved greatly so that in most provinces the two groups work efficiently together as a team. Most laboratories maintain regular informal contact between laboratory and epidemiology staff, and many provincial EPS have now instigated formal monthly surveillance meetings between case investigation, immunization and laboratory staff.

However, discrepancies were noted in many laboratories between the laboratory data held by laboratories, data held by the epidemiology sections, and the computerized data reported on a monthly basis to CAPM. In most provinces visited laboratory staff played little or no part in entering laboratory data into the computers. Furthermore, entered data was not checked by laboratory staff for accuracy or completeness before being transmitted to Beijing. Although the quality of the AFP surveillance computer database held at CAPM has improved greatly over the past two years, active involvement of laboratory staff in validating entered laboratory data would result in much needed further improvements in quality and accuracy. Feedback of surveillance information to laboratory staff was found to be inadequate in several laboratories. CAPM publishes summary reports of surveillance data and indicators, but this information often does not reach laboratory staff.

3.2.2 Recommendations

(1) Laboratory staff should be given greater responsibility for data entered into the computer database transmitted to CAPM on a monthly basis. Before data is transmitted, laboratory staff should be given the opportunity to check for errors and omissions.

(2) Current information feedback mechanisms should be reviewed and improved to ensure that information is received by laboratory staff.

3.3 Laboratory supplies and equipment

3.3.1 Findings

Although there have been problems with supply and distribution of equipment, most laboratories now have the necessary equipment to carry out the expected tasks. Some laboratories still lack adequate biohazard cabinets and replacement HEPA filters for older cabinets. There remains some confusion over which type of cabinets should be used for tissue culture preparation and for handling infectious materials, and this has resulted in inappropriate use of cabinets in some laboratories.

There is a requirement for replacement of biohazard cabinet HEPA filters in several laboratories. Replacement filters have been supplied to many laboratories, but since replacement is not a simple maintenance operation, the filters have not yet been fitted. Although routine maintenance services are available to several of the laboratories, maintenance staff are not able to service specialized equipment such as biohazard cabinets. If clear instructions on installation and maintenance of these cabinets were provided in Chinese, this problem may be overcome.

Some laboratories have received faulty, incomplete or inappropriate equipment. Few laboratories have reported this in a timely manner, however, and equipment has remained unused in the laboratory. Establishment of a system for feedback of information on equipment received in laboratories, its condition on receipt and any problems with installation or maintenance, would allow a more effective response to receipt of faulty or inappropriate equipment.
3.3.2 Recommendations

(1) The current mechanisms for distribution and installation of laboratory equipment and supplies should be reviewed and improved to ensure that laboratories receive the equipment and supplies they need. Improvements should include a formal system for tracking equipment and supplies during distribution within China, and feedback from the laboratories detailing condition of equipment on receipt and any installation problems encountered.

(2) Efforts should be made to supply clear instructions, written in Chinese and English, on installation and maintenance of all essential laboratory equipment.

4. ACKNOWLEDGEMENTS

The international and national team members would like to express their gratitude to the Ministry of Health, Chinese Academy of Preventive Medicine, and all levels of the Provincial Health Bureau for their help, support and generous hospitality in making this a successful review. The participation and continued support of Vice-Minister Dr Yin Dakui, Dr Wang Zhao, Dr Wang Ke-An, and Dr Yu Jingjin are greatly appreciated by all review members.
ANNEX 1

MAP SHOWING LOCATIONS OF THE 25 PROVINCES VISITED
## REVIEW TEAM MEMBERS AND PROVINCES VISITED, 13-23 OCTOBER 1997

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CHECK LIST USED TO REVIEW LABORATORY RESULTS AND PERFORMANCE

Check List for Annual WHO Accreditation of National Poliovirus Laboratories

Dates of Review: ____________ Accreditation for Calendar Year: ____________
Laboratory: __________________________
Address: ___________________________
Phone: ____________ Fax: ____________ E-mail: ____________
Head of Institution: __________________________
Head of Laboratory: __________________________
Technical Supervisor: __________________________
Reviewers: __________________________

If Laboratory is accredited by a National Authority, indicate name of Authority and current accreditation status: __________________________

Part I: Summary of Review

Conclusions (check one):

_____ Laboratory meets accreditation requirements

_____ Laboratory needs assistance to meet accreditation requirements

Findings:

1. AFP test results reported 28 days: _____ %
2. Number of specimens tested: _______
3. NPEV isolation rate: ______% 
4. Isolates confirmed by RRL: ______% 
5. Most recent PT result: ______% 
6. Operating procedures and work practices: ______% 

Summary, comments and recommendations attached.

May 8, 1997
Check List for Annual WHO Accreditation of National Poliovirus Laboratories

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 within 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. Test 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 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 is reviewed annually by WHO and is based on laboratory performance during the immediately preceding 12 months with complete data.

Six criteria for accreditation:

1. Test results are reported by the laboratory on 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 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. In such situations, the laboratory may meet this criterion by providing interim test results to the EPI programme within 28 days and full results within 14 days thereafter.

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

3. The annual non-polio enterovirus (NPEV) isolation rate from all stool specimens is 10%.
   The NPEV isolation rates in some tropical areas may exceed 30%. Rates may be < 10% in some areas with cool seasons, high elevations, low population densities, or high levels of sanitation. Adjustments in anticipated rates, in consultation with the Regional Laboratory Coordinator, may be required for laboratories in these situations.

4. The accuracy of poliovirus detection and identification among all virus isolates is 80%.
   Accuracy is determined by the agreement in test results on all poliovirus isolates and all
NPEV isolates (not to exceed 20) submitted to the Regional Reference Laboratory (RRL) by the National Laboratory during the 12 month review period.

5. The score on the most recent WHO approved proficiency test is 80%.
   Proficiency test (PT) results must be reported within 60 days of panel receipt.

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

Laboratories that perform test procedures other than those recommended by WHO should provide documentation that such procedures, when used in their laboratories, are equivalent in specificity and sensitivity to WHO poliovirus procedures.

A laboratory that achieves less than the passing score on any one of the applicable six criteria will be placed in provisional status. The Regional Laboratory Coordinator and the staff from the laboratory will work together to:
   o Identify areas where improvement is needed.
   o Develop and implement a work plan.
   o Arrange for an accredited laboratory to perform duplicate tests on all specimens or a sub-set of specimens.
   o Monitor laboratory progress.
   o Provide for re-testing where required.
   o Continue steps to achieve full accreditation.

This check list is designed primarily for Laboratories in regions that perform AFP surveillance. Applicable components of criteria 2-6 may be used for laboratories in other regions.

The check list consists of four parts. Part I summarizes the findings of the review and the data on which accreditation is based. Part II provides a profile of the laboratory and serves as a check-list to identify resource needs. Part III provides a worksheet to calculate and record laboratory performance for criteria #1 through #5 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 IV is a check-list for evaluation of laboratory operating procedures and practices for criterion #6.

This check list 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.

Laboratories should be notified in advance of the accreditation review and provided a copy of this form to assist in gathering information.
Part II: Laboratory Profile

1. Staff
   1.1 Number of scientific (s) and technical (t) staff assigned full-time to poliovirus laboratory: s __ t __
       a. With 2 years or more polio laboratory experience: s __ t __
       b. With extramural poliovirus training: s __ t __
   1.2 Part-time staff: Number: s __ t __
       Total equivalent time: s __ t ___

Comments and recommendations:

2. Space
   2.1 Total m² available: ________
   2.2 Number of rooms: ________

Comments and recommendations:
### 3. Equipment on Hand

<table>
<thead>
<tr>
<th>Items</th>
<th>Quantity</th>
<th>Number</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoclave, large, or bench top for small lab</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balance, with power adaptor</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cabinet, clean bench and replacement filter</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cabinet, class II safety and replacement filter</td>
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<tr>
<td>Centrifuge, low speed, refrigerated</td>
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<td></td>
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<tr>
<td>Computer, with software</td>
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<td>Counting chambers</td>
<td>2</td>
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<tr>
<td>Displacement pipettes, 100-1000</td>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>Displacement pipettes, 20-200</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispenser, repeated</td>
<td>2</td>
<td></td>
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<tr>
<td>Fax machine</td>
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<td></td>
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<td>Freezer, -20 C, household, non-frost free, chest type</td>
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<tr>
<td>Incubator, CO₂, and spare regulator</td>
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<tr>
<td>Incubator, standard</td>
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<td>Liquid nitrogen container, 50 L for reserve nitrogen</td>
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<td>Liquid nitrogen storage system</td>
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<tr>
<td>Media filtration system, autoclavable, and accessories</td>
<td>2</td>
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<td></td>
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<tr>
<td>Meter, pH, hand held with spare electrodes</td>
<td>1</td>
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<tr>
<td>Microscope, inverted</td>
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<tr>
<td>Microscope, standard</td>
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<td>Mixer, vortex</td>
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<td>Oven, hot air sterilizing</td>
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<td>Refrigerator, household, 4 C</td>
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<tr>
<td>Stirrer, heated, magnetic with bars</td>
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<tr>
<td>Storage system for chest freezer</td>
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<tr>
<td>Test tube rack for 16 mm tubes</td>
<td>12</td>
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<tr>
<td>Water distiller, double or triple, glass</td>
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<tr>
<td>Water deionizer (cartridge)</td>
<td>1</td>
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<tr>
<td>Water bath</td>
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**Comments and recommendations:**
Annex 3

4. Basic Supplies

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<thead>
<tr>
<th>Items</th>
<th>Quantity</th>
<th>Number on hand</th>
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<tbody>
<tr>
<td>Bottles, 60 ml</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>250 ml</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>125 ml</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>500 ml</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>1 L</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Bulbs (for pipette)</td>
<td>1 pk/12</td>
<td></td>
</tr>
<tr>
<td>Cryovials (2 ml)</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>(4 ml)</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Cylinders, graduated 500 ml</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>100 ml</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Pipette, glass, serological, 1 ml</td>
<td>2 pk/12</td>
<td></td>
</tr>
<tr>
<td>2 ml</td>
<td>2 pk/12</td>
<td></td>
</tr>
<tr>
<td>5 ml</td>
<td>2 pk/12</td>
<td></td>
</tr>
<tr>
<td>10 ml</td>
<td>2 pk/12</td>
<td></td>
</tr>
<tr>
<td>Pipette, 25 ml, glass</td>
<td>1 pk/12</td>
<td></td>
</tr>
<tr>
<td>Thermometers, 0-100 C</td>
<td>6</td>
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</tbody>
</table>

Comments and recommendations:
5. Supplies and Reagents on Hand for Testing 100 Specimens for Poliovirus Isolation

<table>
<thead>
<tr>
<th>Items</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beads, glass</td>
<td>1 Kg</td>
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<tr>
<td>Chloroform</td>
<td>2 liters</td>
</tr>
<tr>
<td>DMSO</td>
<td>3 pk of 5x5 ml ampules</td>
</tr>
<tr>
<td>Dropper, disposable with bulbs</td>
<td>2 boxes/200</td>
</tr>
<tr>
<td>Flask, TC, 150 cm³</td>
<td>1 case/500</td>
</tr>
<tr>
<td>Flask, TC, 25 cm³</td>
<td>1 case/500</td>
</tr>
<tr>
<td>Fungizone</td>
<td>30 pk</td>
</tr>
<tr>
<td>Gloves, latex disposable, medium</td>
<td>100 pairs</td>
</tr>
<tr>
<td>Glutamine</td>
<td>200 g</td>
</tr>
<tr>
<td>Hanks BSS</td>
<td>10 liters</td>
</tr>
<tr>
<td>MEM/HEPES</td>
<td>10 liters</td>
</tr>
<tr>
<td>Microtiter plates (flat bottom, sterile)</td>
<td>100 plates</td>
</tr>
<tr>
<td>Microtiter plate seals</td>
<td>100</td>
</tr>
<tr>
<td>PBS</td>
<td>1 liter</td>
</tr>
<tr>
<td>Penicillin/streptomycin</td>
<td>40 pk</td>
</tr>
<tr>
<td>Phenol red</td>
<td>25 g</td>
</tr>
<tr>
<td>Pipetman tips, disposable, 200</td>
<td>1000</td>
</tr>
<tr>
<td>Pipetman, tips, disposable, 1000</td>
<td>1000</td>
</tr>
<tr>
<td>Serum, fetal bovine</td>
<td>3 liters</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>1 Kg</td>
</tr>
<tr>
<td>Trypan blue</td>
<td>1 pk</td>
</tr>
<tr>
<td>Trypsin lyophilized</td>
<td>30 pk</td>
</tr>
<tr>
<td>Tubes, CC, glass, 16x125</td>
<td>2 cases/500</td>
</tr>
<tr>
<td>Tube caps for CC</td>
<td>1000</td>
</tr>
<tr>
<td>Tubes, 15x85, sterile glass capped</td>
<td>1000</td>
</tr>
<tr>
<td>Tubes, centrifuge (Plastic 50 ml)</td>
<td>100</td>
</tr>
<tr>
<td>Versene (EDTA)</td>
<td>100 ml</td>
</tr>
</tbody>
</table>

Comments and recommendations:
Annex 3

Part III: Laboratory Performance in Previous 12 Months

Dates: from \_
\_ \_ \_ to \_
\_ \_ \_ \_

1. Percentage of AFP Test Results Reported Within 28 Days of Specimen Receipt: ______ %

1.1 Number of AFP cases tested: ______
   a. Percentage with 2 stools: ______(%) 
   b. Number with test results reported within 28 days: ______ 
   c. Percentage with specimens collected within 14 days of onset of paralysis: ______(%) 
   d. Percentage with specimens received by the laboratory within 3 days of collection: ______(%) 

1.2 Percentage of AFP specimens received by the laboratory in good condition: ______(%) 

Comments and recommendations:

2. Total Number of Specimens Tested from all sources: ______
   a. For Polio:
      AFP ______
      contacts ______
      special surveys ______
      environmental ______
      vaccine potency assays ______
      other ______
   b. For all other viruses: ______

Comments and recommendations:
3. Non-polio enterovirus (NPEV) Isolation Rate from feces: ____ %

Comments and recommendations:

4. Percent Virus Isolates with Identification Confirmed By RRL: ____ %
   4.1 Number of polioviruses isolated: ____
       Forwarded to RRL: ____
       Confirmed by RRL: ____
   4.2 Number of NPEV isolated: ____
       Forwarded to RRL: ____
       Confirmed by RRL: ____

Comments and recommendations:

5. Result of Most Recent Proficiency Test: ____ %  Date of Test: _/ _/ _

Comments and recommendations:
Part IV: Laboratory Operating Procedures and Work Practices

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

Comments and recommendations:

2. Staff (4%)  
   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%)  
   3.1 The lines of supervision and accountability are clear: ________  
   3.2 Supervisor critically reviews test results: ________  

Comments and recommendations:
Annex 3

4. Cell Lines (15%)

4.1 Written appropriate protocols are available for:
   a. Freezing and recovery of cells: __________
   b. Routine passage of cells: __________

4.2 RD and HEp2 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 after 6 months or 26 passages: __________

4.7 Monolayers remain healthy for 5-7 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, and stored at indicated temperatures: __________

Comments and recommendations:

5. Stool Specimens (15%)

5.1 Line listings are maintained for all specimens, including where applicable:
   a. Lab/EPID number: __________
   b. Name: __________
   c. Sex: __________
   d. Date of birth: __________
   e. Address: __________
   f. Number of doses of vaccine received: __________
   g. Date of last vaccine dose: __________
   h. Date of paralysis onset: __________
   i. Sequence and date of stool collection (i.e. 1st or 2nd): __________
   j. Date received by lab: __________
   k. Condition of stool: __________
   l. Amount: __________
   m. Date specimen inoculated: __________
   n. Results: __________
   o. Date of reporting: __________
5.2 A written protocol for processing specimens is available: __________
5.3 Specimens are processed by chloroform extraction in accord with WHO protocols: ______
5.4 Extracts are stored at -20°C if not inoculated on same day as processed: __________
5.5 All potentially infected clinical materials are processed in a biological safety cabinet: ______
5.6 Original specimens are appropriately labeled and stored at -20°C for at least 12 months: ____
5.7 Specimens, extracts, all virus isolates, and other potentially infectious materials are stored separately from non-infectious materials in designated freezers and refrigerators: ______
5.8 Wild viruses are stored in separate, clearly marked containers with limited access: ______

Comments and recommendations:

6. Virus Isolation (15%)

6.1 Written protocols are available: __________
6.2 Extracts are inoculated within 7 days of processing: __________
6.3 Extracts are inoculated on RD and HEp2 at the same time: __________
6.4 The first and second specimens from each patient are processed and inoculated separately, never combined: __________
6.5 Records are maintained on daily observations of inoculated cells: __________
6.6 Two sequential passages of 5-7 days are performed in two cell lines before recording as negative: __________

Comments and recommendations:
7. Virus Identification (15%)

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 ml 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 Enterovirus typing sera are used: 
7.6 Virus typing worksheets are retained as permanent records: 
7.7 80% of poliovirus isolates are forwarded to designated RRL within 14 days of identification: 
7.8 Isolates are stored at -20 C or lower for at least 3 years: 
7.9 Vials are clearly labeled: 
7.10 Permanent records are maintained on the identity and location of all isolates: 

Comments and recommendations:

8. Biosafety (10%)

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. Decontaminating all infectious or clinical waste before discarding: 
   d. Decontaminating lab work surfaces: 
   e. Immunizing staff against polio and hepatitis B: 
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:

Comments and recommendations:
Annex 3

9. Cooperation with EPI Staff (10%) Score: __
   9.1 Lab and EPI staff communicate/meet at least monthly: _________
   9.2 EPI staff are contacted if specimens arrive without adequate information or EPID numbers:
   9.3 Lab staff member(s) serve on:
      a. AFP review committees: _________
      b. NID planning committees: _________

Comments and recommendations:

10. Equipment (4%) Score: __
    10.1 Equipment is functioning and in good condition: _________
    10.2 Equipment is maintained periodically as recommended and dates recorded: _________
    10.3 Equipment location is conducive to optimal performance: _________
    10.4 Records are kept on daily temperature readings of incubators, refrigerators, and freezers:
        _________
    10.5 CO₂ incubators are calibrated at least monthly: _________

Comments and recommendations:

11. Supplies (4%) Score: __
    11.1 Current inventories are maintained: _________
    11.2 Adequate time is allowed for replenishing supplies: _________

Comments and recommendations:

Total Score: _______
# SUMMARY TABLE OF REVIEW FINDINGS AND PROPOSED ACTIONS

<table>
<thead>
<tr>
<th>Province</th>
<th>Recommendation</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHAANXI</td>
<td>Pass</td>
<td>Review after 12 months</td>
</tr>
<tr>
<td>HEBEI</td>
<td>Pass</td>
<td>Review after 12 months</td>
</tr>
<tr>
<td>BIEJING</td>
<td>Pass</td>
<td>Review after 12 months</td>
</tr>
<tr>
<td>GUANGDONG</td>
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<td>Review after 12 months</td>
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</tr>
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</tr>
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<tr>
<td>JIANGSU</td>
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<td>Improve and review after 6 months</td>
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<td>QINGHAI</td>
<td>Fail</td>
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SUMMARY AND RECOMMENDATIONS FOR NINGXIA PROVINCE

Laboratory: Yinchuan, Ningxia

Date of Review: 15 October 1997

Reviewers: Dr Harry Caussy, WHO/SEARO
Dr Lu Li

Review outcome: Provisionally accredited for 1998; review performance after 6 months

SUMMARY

Staff
This laboratory has 3 experienced and dedicated personnel, one of whom has had extramural training. The workload is relatively low, and the staffing level is adequate. There is a requirement for extra-mural training for at least 1 staff member, and in-service training, especially in tissue culture procedures, for all staff.

Equipment and Supplies
The laboratory has most of the essential core equipment except for a pH meter. The hot air sterilizer oven and the CO2 incubator are non-functional. Spare bulbs are required for the inverted microscope and replacement HEPA filters are needed for the clean benches and biological safety cabinet. It has not experienced any difficulty in obtaining regular laboratory supplies except for HEPES buffered MEM. No systematic inventory of supplies and consumables is kept. Four rooms are available for laboratory use and space allocated is adequate for staff to follow good laboratory practices.

Procedures
a) Tissue culture
Cell lines were changed in 1995, and since then the NPEV isolation rate has been low. The laboratory needs to be supplied with fresh stocks of RD and Hep2 cells.

b) Isolation and typing
The laboratory has obtained at least 80% in the annual proficiency test for the past 3 years. In 1994 the NPEV isolation rate was 28%. For the period under review, however, the NPEV isolation rate was less than 1% (1/167). Five poliovirus isolates have been forwarded to the National Laboratory for intratypic differentiation. Results have been obtained on only two of these; both were confirmed by the National Laboratory.

Coordination
The rapport between the EPI unit and the laboratory is excellent, both being in the same building.
Annex 5

RECOMMENDATIONS

1. The laboratory meets only 5 of the 6 criteria set by WHO for accreditation, having failed to reach the expected NPEV isolation rate. The laboratory should be regarded as provisionally accredited, but:
   • fresh RD and Hep2 cells should be provided
   • when fresh cell lines have been established, and with in the next 6 months, the laboratory should re-test at least 100 specimens collected over the past 12 months
   • the NPEV rate in the re-tested specimens should be reviewed after 6 months, if the NPEV rate reaches expected levels the laboratory should be regarded as fully accredited.

2. Replacement HEPA filters should be procured and fitted in the clean air cabinet and the biological safety cabinet

3. The CO2 incubator and hot air sterilizer oven should be assessed for repair or replacement and appropriate action taken.

4. A pH meter and spare bulbs for the inverted microscope should be procured

5. HEPES buffered MEM should be procured for use in cell work

6. An inventory of supplies must be established and maintained to anticipate needs

Checklist summary:

Findings:
- AFP results within 30 days: 100%
- Number of specimens tested: 167
- NPEV isolation rate: 0.6%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 88%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 12
- Stool specimens: 15
- Virus isolation: 15
- Virus identification: 13
- Biosafety: 8
- Cooperation: 9
- Equipment: 2
- Supplies: 2
SUMMARY AND RECOMMENDATIONS FOR SHAANXI PROVINCE

Laboratory: Xian, Shaanxi
Date of Review: 17 October 1997
Reviewers: Dr Harry Caussy, WHO/SEARO
Dr Lu Li

SUMMARY

Staff
This laboratory has an experienced and dedicated staff of 3. Only 1 of the staff has received extramural training.

Equipment and supplies
The laboratory has all the essential core equipment maintained in good conditions. There is no CO2 incubator, but the laboratory has 2 standard incubators. The laboratory also lacks a pH meter. It requires a replacement HEPA filters for the biological safety cabinet and clean bench, and deionizer cartridges for the water deionizer. It has not experienced any difficulty in obtaining regular laboratory supplies.

Procedures
a) Tissue culture
Tissue culture procedures appear to be good and cells are maintained in good condition.

b) Isolation and typing
The laboratory obtained a score of 100% in the annual proficiency testing for the past 4 years. Calculation of the NPEV isolation rate of 13% for the period of the review was made on the positivity rate of AFP cases; a slightly lower rate was obtained when calculated on specimens received. Clear seasonality of NPEV isolation was observed, however, with a summer peak recorded for 1995, 1996 and 1997. The laboratory sent 4 polio isolates to the National Laboratory for confirmation; all were confirmed.

The laboratory follows the WHO recommended standard of procedure including all the major aspects of biosafety.

Coordination
Rapport between the EPI unit and the laboratory is excellent both being in the same building.
RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. An additional staff member should be recruited and trained so that there is adequate cover when other staff are absent for holidays and sickness.
3. Replacement HEPA filters for the biological safety cabinet and clean air bench together with a pH meter and spare cartridges for the water deionizer, should be procured.
4. All reagents should have an expiry date for use recorded, and temperature monitoring records maintained on all incubators, refrigerators and freezers.

Checklist summary:

Findings:
- AFP results within 30 days: 88%
- Number of specimens tested: 448
- NPEV isolation rate: 13%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 94%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 12
- Stool specimens: 15
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 8
- Cooperation: 10
- Equipment: 3
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR XINJIANG PROVINCE

Laboratory: Urumqi, Xinjiang

Date of Review: 19 October 1997

Reviewers: Dr Harry Caussy, WHO/SEARO
Dr Lu Li

Review outcome: Not accredited for 1998

SUMMARY

Staff
Laboratory has 3 experienced technical staff, but none have received extra-mural training.

Equipment and supplies
The laboratory has 4 rooms and space appears to be adequate, but specimens are handled on the open bench, not in the biohazard cabinet. It has the necessary core equipment but installation of new equipment appears to be a problem; a new centrifuge and liquid nitrogen storage system have been received but have not been put into use. The laboratory has no pH meter, and the water dionizer cannot be used because of a missing pump. The laboratory appears to be receiving basic supplies and consumables.

Procedures
a) Tissue culture
Laboratory staff follow standard WHO-recommended procedures, but the quality of tissue cultures could be improved if staff were given appropriate training.

b) Isolation and typing
This laboratory has obtained 100% on the most recent proficiency test. The NPEV isolation rate for the period under review was 4%, but a clear seasonality of NPEV isolation was observed, with a summer peak of above 30%. The laboratory sent 5 poliovirus isolates to the National Laboratory and all were confirmed, but of 6 NPEV isolates sent only 4 were confirmed as NPEV, the other 2 were found to be vaccine-related poliovirus isolates. This laboratory is located in a province that borders countries with wild polioviruses and must be able to accurately identify any polioviruses therefore it must be technically competent to handle all specimens.

The ability of the staff to resolve technical problems appears limited, and as a consequence the standard of Good Laboratory Practice is not adequate for identification of viruses or the maintenance of laboratory information.

Coordination
The laboratory has good rapport with the EPI Unit, but general record keeping is not good.
Annex 7

RECOMMENDATIONS

1. The laboratory cannot be regarded as fulfilling the role required, and cannot be regarded as accredited.

2. A laboratory expert should be sent to work with laboratory staff for at least one month to strengthen the laboratory and improve laboratory performance.

3. Extra mural training should be provided as a matter of urgency for at least one staff member.

4. A biosafety cabinet should be provided for processing stool specimens.

5. Record keeping for laboratory data should be improved.

6. Performance of the laboratory should monitored through regular re-testing of virus isolates and a selection of negative specimens by the National Laboratory and the laboratory reviewed again in 12 months.

Checklist summary:

Findings:
- AFP results within 30 days: 82%
- Number of specimens tested: 213
- NPEV isolation rate: 4%
- Isolates confirmed: 82%
- Proficiency test result: 100
- Operating procedures and practices: 75%

Breakdown of review scores:
- Space: 3
- Staff: 4
- Supervision: 4
- Cell lines: 10
- Stool specimens: 9
- Virus isolation: 13
- Virus identification: 12
- Biosafety: 7
- Cooperation: 10
- Equipment: 1
- Supplies: 2
SUMMARY AND RECOMMENDATIONS FOR SHANXI PROVINCE

Laboratory: Taiyuan, Shanxi

Date of Review: 15 October 1997

Reviewers: Dr Mangalam Sinniah, IMR, Kuala Lumpur, Malaysia
Dr Ferns Paladin, RITM, Manila, Philippines
Dr Liu Aihua

Review outcome: Not accredited for 1998

SUMMARY

This laboratory facility is situated in an old building and there was electricity failure on the day of our visit. The room space is sufficient.

Staff
There was only one technologist doing full-time bench-work in the polio laboratory. The others, 5 part-time staff were not around to be interviewed. The designated staff was well trained by the National Laboratory in routine work, but not able to trouble shoot. The supervision appeared to be unsatisfactory.

Equipment and supplies
Generally most of the required equipment was available. They share a CO2 incubator with another laboratory. There is also no pH meter available. The reagents Fungizone and foetal calf serum are difficult to obtain.

Procedures
Standard operating procedures for tissue culture, isolation and typing were being closely followed.
There was no documentation of refrigerator or freezer temperatures and no documentation of cell passages and storage history.

Biosafety
There were no gloves available for staff use; no Biosafety Manual and standard biosafety rules were not enforced.

Coordination
Coordination between the laboratory and the EPI staff were less than ideal and could be improved. The laboratory staff do not verify the data being input into the EPI computer.
Annex 8

Recommendations:

1. The laboratory cannot be regarded as fulfilling the role required, having failed to achieve a passing score on the review checklist. The laboratory cannot be regarded as accredited.

2. At least one more full-time technologist for the polio laboratory should be employed as a matter of urgency, and a training update provided for the first technologist.

3. The possibility of sending a laboratory expert to work with laboratory staff for at least 2 weeks should be explored.

4. Better co-ordination between laboratory and epidemiology staff must be established, this can be achieved through more frequent meetings and review of data.

5. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.

Checklist summary:

Findings:

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<th>Score</th>
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<tr>
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<td>NPEV isolation rate:</td>
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<tr>
<td>Isolates confirmed:</td>
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<tr>
<td>Proficiency test result:</td>
<td>100%</td>
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<tr>
<td>Operating procedures and practices:</td>
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Breakdown of review scores:

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<td>Supervision</td>
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<tr>
<td>Cell lines</td>
<td>10</td>
</tr>
<tr>
<td>Stool specimens</td>
<td>12</td>
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<td>Virus isolation</td>
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SUMMARY AND RECOMMENDATIONS FOR HEBEI PROVINCE

Laboratory: Baoding, Hebei
Date of Review: 16 October 1997
Reviewers: Dr Mangalam Sinniah, IMR, Kuala Lumpur, Malaysia
Dr Ferns Paladin, RITM, Manila, Philippines
Dr Liu Aihua


SUMMARY

Staff, equipment and supplies: This lab is generally a well set up facility with sufficient space and staff who are well trained. There are 6 scientific staff. All indicators have been reached with the lab review score being 92%.

There are no problems with supplies the only complaint being insufficient RIMV anti sera and good quality fungisone.

Procedures: Most of the documentation were ready and available for inspection. The only ones missing were records of CO₂ incubator calibration and inventories for anti sera and lab reagents.

Standard operating procedures were followed closely in all tissue Culture work.

Biosafety: There were no written biosafety manuals although basic biosafety rules were being observed.

Coordination: Between EPI and lab staff was good, but the lab should get to review computer data after entry for tracking input errors.

Recommendations:

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. Biosafety regulations should be provided and implemented,
3. Inventories of reagents and poliovirus typing antisera should be established and maintained,
4. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures,
5. Retraining and refresher training for laboratory staff, and training in computer data management should be provided.
Checklist summary:

Findings:
- AFP results within 30 days: 90%
- Number of specimens tested: 525
- NPEV isolation rate: 11%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 92%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 15
- Stool specimens: 15
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 8
- Cooperation: 8
- Equipment: 2
- Supplies: 2
SUMMARY AND RECOMMENDATIONS FOR BEIJING

Laboratory: Beijing

Date of Review: 18 October 1997

Reviewers: Dr Mangalam Sinniah, IMR, Kuala Lumpur, Malaysia
Dr Fems Paladin, RITM, Manila, Philippines
Dr Liu Aihua


SUMMARY

STAFF
The number was sufficient to handle the workload. All had extramural training. Needs update on the current WHO protocol.

EQUIPMENT
The laboratory was well-equipped; the equipment were functioning, well and maintained in good condition. Records of service maintenance were not available (on hand) for the reference of the laboratory staff.

SUPPLIES
All basic supplies were available; there were no problems with procurement. Fungizone was said to be toxic. HEPES and Trypan blue were not in use.

PROCEDURE
The laboratory staff had a good grasp of the cell culture techniques and poliovirus isolation and identification testing strategy. Enterovirus/RIVM pool was not available.

BIOSAFETY
Biosafety procedures are enforced; Written general instructions are available but actual practices being carried out are not noted.

COORDINATION
There was good coordination with the EPI and laboratory staff. Communication lines were open, however, data management support from EPI staff needs improvement. Hard copy of collated data not provided to lab staff for review/verification.
Annex 10

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. Biosafety regulations should be provided and implemented,
3. Inventories of reagents and poliovirus typing antisera should be established and maintained,
4. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures,
5. Retraining and refresher training for laboratory staff, and training in computer data management should be provided.
6. Regular supervisory review should be made to ensure that the procedures are enforced.
7. Laboratory data entered into the computer should be reviewed by laboratory staff before it is sent to CAPM.

Checklist summary:

Findings:

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<tr>
<td>NPEV isolation rate:</td>
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<td>Isolates confirmed:</td>
<td>100%</td>
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<tr>
<td>Proficiency test result:</td>
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<tr>
<td>Operating procedures and practices:</td>
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Breakdown of review scores:

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<td>Staff</td>
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<td>Supervision</td>
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<td>Cell lines</td>
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<td>Stool specimens</td>
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<td>Virus isolation</td>
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<td>Supplies</td>
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SUMMARY AND RECOMMENDATIONS FOR TIANJIN

Laboratory: Tianjin
Date of Review: 20 October 1997
Reviewers: Dr Mangalam Sinniah, IMR, Kuala Lumpur, Malaysia
Dr Ferns Paladin, RITM, Manila, Philippines
Dr Liu Aihua

Review outcome: Provisionally accredited for 1998: review performance after 6 months

SUMMARY

Staff
The number was sufficient to handle the workload. All had extramural training but not in the recent past. Experienced ranged from 5-30 yr.

Equipment and supplies
The laboratory was well-equipped: the equipment were functioning well and maintained in good condition however service record was not available. No documentation of daily temperature readings. Location of Clean hood and BSC II was prone to environmental contamination. Dry incubator for inoculated cultures was obsolete. CO2 incubator not available hence Virus typing is performed on tubes. Distilling apparatus not installed apparently because of poor water quality.

PROCEDURE
The laboratory staff had some problems with maintaining the RD cells in good condition: this was apparent in the inoculated cultures because cells were passed every 3 days. and maintained up to 57 passages for about 8 months. Records of cell passage histories, storage in liquid nitrogen were incomplete and not made in a traceable manner.
A clear grasp of troubleshooting problems in cell maintenance and poliovirus isolation strategy seems to be lacking. Errors in entry of result findings in the observation records were noted.
Enterovirus typing sera not available.

BIOSAFETY
Biosafety procedures are enforced; Written general instructions are available but actual practices being carried out are not noted.

COORDINATION
There was good coordination with the EPI and laboratory staff. Communication lines were open, however, data management support from EPI staff needs improvement.
Hard copy of collated data not provided to lab staff for review/verification.
Annex 11

RECOMMENDATIONS

1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as provisionally accredited,
2. fresh RD and Hep2 cells should be provided
3. Retraining on current WHO-recommended procedures should be provided as a matter of urgency.
4. Location of the tissue culture clean bench and biosafety cabinet should be improved to meet with the requirements of Good Laboratory Practice,
5. Support should be sought for the provision of a standard incubator, CO2 incubator, and accessory supplies needed to install the distilling apparatus,
6. Record keeping for cell passage histories and storage of cells in liquid nitrogen should be improved,
7. Technical supervision from the laboratory supervisor should be improved,
8. Biosafety regulations should be provided and implemented,
9. Inventories of reagents and poliovirus typing antisera should be established and maintained,
10. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures.
11. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.

Checklist summary:

Findings:
- AFP results within 30 days: 100%
- Number of specimens tested: 311
- NPEV isolation rate: 14.5%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 80%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 3
- Cell lines: 10
- Stool specimens: 14
- Virus isolation: 10
- Virus identification: 10
- Biosafety: 8
- Cooperation: 9
- Equipment: 4
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR JIANGXI PROVINCE

Laboratory: Nanchang, Jiangxi

Date of Review: 15-16 October 1997

Reviewers: Dr H. Shimizu
Dr H. Yoshikura
Dr Liu Aihua

Review outcome: Provisionally accredited for 1998; review performance after 6 months

SUMMARY

STAFF
Sufficient: Six persons with laboratory experience for more than 2 years. Two were trained either in RRL or in NIID Japan.

EQUIPMENT / SUPPLY:
Laboratory space is sufficiently large. Clean and dirty areas are separated. Minimum level of equipments is available. The liquid nitrogen is not used for cell storage. One of the two chambers of the CO2 incubator is broken.

PROCEDURES
T/C: The RD cells are not in the perfect condition: Hep-2 cells are OK. The bacterial or fungal contamination appeared frequent.
Isolation / Typing: Viral isolation is performed with 24-well plates: probably due to contamination, observation was sometimes too short, only for 3-4 days.

BIOSAFETY: Satisfactory.

COORDINATION: Coordination between lab and EPI staff is good; they share the same office room. Lab staff are invited to be members of AFP diagnosis committee and also to NID planning committee.

RECOMMENDATIONS
1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as provisionally accredited,
2. fresh RD and Hep2 cells should be provided
3. Retraining on current WHO-recommended procedures should be provided as a matter of urgency,
4. Broken equipment should be repaired or removed from the laboratory for disposal,
5. A liquid nitrogen storage system for RD and Hep2 cells should be established as soon as possible,
6. Virus isolation should be carried out in tubes, not 24-well plates, as this leads to contamination of cultures,
7. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.
Annex 12

Checklist summary:

Findings:
- AFP results within 30 days: 94%
- Number of specimens tested: 228
- NPEV isolation rate: 30%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 84%

Breakdown of review scores:
- Space: 3
- Staff: 4
- Supervision: 4
- Cell lines: 10
- Stool specimens: 14
- Virus isolation: 10
- Virus identification: 13
- Biosafety: 10
- Cooperation: 10
- Equipment: 2
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR GUANGDONG PROVINCE

Laboratory: Guangzhou, Guangdong
Date of Review: 17 October 1997
Reviewers: Dr H. Shimizu
Dr H. Yoshikura
Dr Liu Aihua


SUMMARY

STAFF: Sufficient. Four persons with extramural polio training. All the staff are well trained and have expertise in the polio laboratory work.

EQUIPMENT /SUPPLY: The laboratory space is large. The clean and dirty areas are separated. The laboratory is well equipped. However, the only one CO2 incubator which is functioning has a trouble in one chamber. The center has a central service for the sterilization, decontamination, and supply of sterilized glass wares. The room for virus isolation and typing is not air-conditioned.

PROCEDURES

T/C: The both RD and Hep-2 are in a perfect condition. The cells at younger passages are stored in liquid nitrogen. The cells were renewed every 10 passages after thawing.

Isolation /Typing: The specimens for inoculation is routinely kept at 4 C overnight, which does not follow the WHO protocol. Roller tubes are used for virus isolation. Virus preparations with slightly too high titers were used for typing. Bacterial or fungal contamination during the isolation or typing appears infrequent. Laboratory records are perfect. This laboratory is capable of doing more advanced level of testing.

BIOSAFETY: No problem.

COORDINATION: Perfect. The EPI and laboratory staff share the same data base using the same computer.

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. Support should be sought for supply of a replacement CO2 incubator
3. Support should be sought for supply of an air conditioner unit for the virus isolation room, as during the hot season the temperature of the incubator may not be kept properly.
Annex 13

Checklist summary:

Findings:
- AFP results within 30 days: 91%
- Number of specimens tested: 691
- NPEV isolation rate: 11.4%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 98%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 15
- Stool specimens: 14
- Virus isolation: 15
- Virus identification: 14
- Biosafety: 10
- Cooperation: 10
- Equipment: 4
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR HAINAN PROVINCE

Laboratory: Haikou, Hainan
Date of Review: 20 October 1997
Reviewers: Dr H. Shimizu
           Dr H. Yoshikura
           Dr Liu Aihua

Review outcome: Provisionally accredited for 1998; review performance after 6 months

SUMMARY

STAFF: As the province is small and the specimens are not many, the three staff are enough for handling. None of the staff have received extramural training, and their knowledge of the polio isolation and typing appeared slightly outdated.

EQUIPMENT/SUPPLY: The laboratory space is rather narrow, but well organized. The clean and dirty area are well separated. All the rooms for laboratory work were air-conditioned. The laboratory has minimum equipments, which are kept in good condition. The CO2 NAPCO incubator procured by the Province is in a perfect condition.

PROCEDURES
T/C: Both RD and Hep-2 cells are apparently in good condition. However, the cells were in very advanced passage levels exceeding 150 p. As the isolation of enteroviruses were going well, the cells seemed well susceptible to viruses.
Isolation/Typing: Viruses were isolated with roller tubes. The microbial contamination during the isolation and typing appeared infrequent. In typing, the back titration is not done. There were not a few viruses which were positive both in RD and Hep-2 cells, but the routine typing was done with Hep-2 only. Therefore, presence of poliovirus in the enterovirus-positive cultures was not entirely excluded. Documentation of record is not perfect; the date of observation is not clearly recorded.

BIOSAFETY: The building has a central service, but has only a pressure kettle-type autoclave. Most contaminated materials were just boiled or burnt with alcohol. The pipettes are decontaminated chemically.

COORDINATION: The laboratory and EPI staff share the same room and the communication appeared good. The chief of the laboratory is a member of AFP diagnosis committee.
RECOMMENDATIONS

1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as provisionally accredited.
2. Retraining on current WHO-recommended procedures should be provided as a matter of urgency.
3. Support should be sought for the provision of a laboratory autoclave,
4. Biosafety regulations should be provided and implemented,
5. Inventories of reagents and poliovirus typing antisera should be established and maintained,
6. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.

Checklist summary:

Findings:
- AFP results within 30 days: 89%
- Number of specimens tested: 156
- NPEV isolation rate: 37%
- Isolates confirmed:
- Proficiency test result: 100%
- Operating procedures and practices: 80%

Breakdown of review scores:
- Space: 3
- Staff: 4
- Supervision: 3
- Cell lines: 12
- Stool specimens: 12
- Virus isolation: 12
- Virus identification: 12
- Biosafety: 6
- Cooperation: 9
- Equipment: 3
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR JILIN PROVINCE

Laboratory: Changchun, Jilin
Date of Review: 15 October 1997
Reviewers: Dr T. Miyamura
Dr M. Hara
Ms Li Yuxin

SUMMARY

1) Staff
Three staff members are all young, enthusiastic and well trained. They co-work very well. They all realize the importance of the program and do their task efficiently.

2) Equipment and supply
CO2 incubator is not working and they gave up to use it. They use candle culture to compensate this problem. Other equipments are basically well maintained and controlled.

3) Processing
a) T/C: Both RD and Hep2C cells looked nicely maintained. However, RD cells presently used is already over 30 passages after they received from the national lab. Cell cultures were done in cabinets sometimes used for virus preparation. The microscope was set in the different room where the cell preparation was done.
   b) isolation and typing: Adequate sera were used and performance seems to be reliable. When we visited, there were no virus isolation trials on-going.

4) Biosafety:
Staffs seemed to be trained for the idea of Biosafety, but it is a little bit doubtful that other workers have the similar education. Room for virus processing and isolation should be clearly marked as such.

5) Coordination:
Coordination to National Lab seems to be good. The lab procedures were faithfully followed after instructions provided by the National lab through its training course. The supervisor of the lab group is also the chief of EPI and their coordination is consequently perfect.
Annex 15

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. Biosafety regulations should be provided and implemented.
3. Better separation should be made between the clean and dirty areas.
4. Support should be sought for supply of a replacement CO2 incubator.
5. Laboratory data entered into the computer should be reviewed by laboratory staff before it is sent to CAPM.

Checklist summary:

Findings:
- AFP results within 30 days: 98%
- Number of specimens tested: 612
- NPEV isolation rate: 12.5%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 88%

Breakdown of review scores:
- Space: 2
- Staff: 4
- Supervision: 3
- Cell lines: 11
- Stool specimens: 14
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 8
- Cooperation: 10
- Equipment: 2
ANNEX 16

SUMMARY AND RECOMMENDATIONS FOR LIAONING PROVINCE

Laboratory: Shenyang, Liaoning

Date of Review: 16-18 October 1997

Reviewers: Dr T. Miyamura
Dr M. Hara
Ms Li Yuxin


Liaoning:

1) Staff
   Three staff members are all young, enthusiastic and well trained. They co-work very well. They all realize the importance of the program and do their task efficiently. The leader (Ms Shun) is now in London for a month, but her duties were efficiently replaced by other members.

2) Equipment and supply:
   CO2 incubator is not working. They use candle culture to compensate this problem. Other equipments are basically well maintained and controlled. Routine use reagents were kept in a room for virus isolation.

3) Processing
   a) T/C: Both RD and Hep2C cells looked nicely maintained, although cultures seemed to be too dense. They intentionally prepared cells one day before our review. The microscope was set in the different room where the cell preparation was done.
   b) isolation and typing: Adequate sera were used and performance seems to be reliable. However, they used virus isolation in a 24 well-plate containing both RD and Hep2C cells. They also tried virus isolation without having uninoculated cell control wells.

4) Biosafety
   As far as the staffs are concerned, they are well trained for the idea of Biosafety, but it is a little bit doubtful that other workers have the similar education. Room for virus processing and isolation should be clearly marked as such (Biohazard label).

5) Coordination: Coordination to National Lab seems to be good as other labs in Jilin and Heilongjiang. The lab procedures were faithfully followed after instructions provided by the National lab through its training course. The coordination to EPI group was good.
RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. The washing room for glassware should be made separate to the other laboratory rooms.
3. Biosafety regulations should be provided and implemented.
4. Retraining and refresher training for laboratory staff, and training in computer data management should be provided.
5. Virus isolation should be carried out in tubes, not 24-well plates.
6. Laboratory data entered into the computer should be reviewed by laboratory staff before it is sent to CAPM.

Checklist summary:

Findings:

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<tr>
<td>AFP results within 30 days:</td>
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<td>Number of specimens tested:</td>
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<td>NPEV isolation rate:</td>
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</tr>
<tr>
<td>Isolates confirmed:</td>
<td>80%</td>
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<td>Proficiency test result:</td>
<td>100%</td>
</tr>
<tr>
<td>Operating procedures and practices:</td>
<td>90%</td>
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Breakdown of review scores:

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</thead>
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<td>Space</td>
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<tr>
<td>Supervision</td>
<td>4</td>
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<tr>
<td>Cell lines</td>
<td>13</td>
</tr>
<tr>
<td>Stool specimens</td>
<td>13</td>
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<tr>
<td>Virus isolation</td>
<td>14</td>
</tr>
<tr>
<td>Virus identification</td>
<td>15</td>
</tr>
<tr>
<td>Biosafety</td>
<td>8</td>
</tr>
<tr>
<td>Cooperation</td>
<td>10</td>
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<tr>
<td>Equipment</td>
<td>2</td>
</tr>
<tr>
<td>Supplies</td>
<td>4</td>
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</tbody>
</table>
ANNEX 17

SUMMARY AND RECOMMENDATIONS FOR HEILONGJIANG PROVINCE

Laboratory: Harbin, Heilongjiang

Date of Review: 20-21 October 1997

Reviewers: Dr T. Miyamura
Dr M. Hara
Ms Li Yuxin


SUMMARY

1) Staff:
Four staff members are all young, enthusiastic and well trained. They co-work very well. They all realize the importance of the program and do their task efficiently. The leader Ms Ma is particularly consistent and her work is reliable. Four members are divided to two groups, and RD cells and Hep2C cells were inoculated totally independently with the stool extracts. Coordination within the group is very good.

2) Equipment and supply:
CO2 incubator is working. Originally the incubator was not so good, but the maintenance people (from the different section of the institute) fixed it and keep checking every week. Other equipments are also well maintained and controlled. Filters were also periodically replaced by these people. Clean bench provided recently from WHO did not function at all. They did not have their in-house pure water supply, but they purchase it weekly from neighbouring Harbin University.

3) Processing:
(a) T/C: Both RD and Hep2C cells looked nicely maintained. Both cells replaced several passages before they are suggested to do so from frozen stocks. Cell cultures were done in a cabinets completely different from the one for virus preparation in a different room.
(b) isolation and typing: Adequate sera were used and performance seems to be reliable. Sera were timely provided by the national lab.

4) Biosafety:
Staffs seemed to be trained for the idea of Biosafety. Room for virus processing and isolation should be clearly marked as such. Wild poliovirus should be kept in special freezer at highest control. Although the freezer was locked but other materials frequently used were also kept in the same freezer.

5) Coordination:
Coordination to National Lab seems to be good. The lab procedures were faithfully followed after instructions provided by the National lab through its training course. The lab group is also assigned as EPI members. The leader of the EPI used to be a lab specialist. Their office is shared with lab and EPI people. Their coordination is consequently perfect.
Annex 17

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. A source of good quality water for laboratory use should be provided.
3. Biosafety regulations should be provided and implemented.
4. Retraining and refresher training for laboratory staff, and training in computer data management should be provided.

Checklist summary:

Findings:
- AFP results within 30 days: 86%
- Number of specimens tested: 692
- NPEV isolation rate: 11.5%
- Isolates confirmed: 100%
- Operating procedures and practices: 98%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 15
- Stool specimens: 14
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 9
- Cooperation: 10
- Equipment: 4
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR SICHUAN PROVINCE

Laboratory: Chengdu, Sichuan
Date of Review: 14-16 October 1997

Reviewers: Dr Walter Dowdle
Dr Zhang Xinglu


SUMMARY

This Laboratory has steadily improved over the last 3 years. The assistance of JICA and CAPM is deeply appreciated. The Laboratory meets all six criteria for accreditation. Several areas continue to need improvement.

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. Biosafety regulations should be provided and implemented.
3. Written protocols should be prepared for all procedures used by the Laboratory.
4. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures.
5. Records of equipment maintenance and performance should be maintained

Checklist summary:

Findings:
- AFP results within 30 days: 81%
- Number of specimens tested: 539
- NPEV isolation rate: 15.9%
- Isolates confirmed: 86%
- Proficiency test result: 100%
- Operating procedures and practices: 88%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 13
- Stool specimens: 14
- Virus isolation: 13
- Virus identification: 12
- Biosafety: 8
- Cooperation: 10
- Equipment: 2
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR YUNNAN PROVINCE

Laboratory: Kunming, Yunnan
Date of Review: 17-18 October 1997

Reviewers: Dr Walter Dowdle
            Dr Zhang Xinglu


SUMMARY

This is an outstanding Laboratory, with good equipment, new facilities, and a highly professional staff. It meets all six criteria for accreditation. If poliovirus were present in any specimen this Laboratory would be certain to find it.

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. Biosafety regulations should be provided and implemented,
3. Written protocols should be prepared for all procedures used by the Laboratory.
4. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures,
5. Records of equipment maintenance and performance should be maintained

Checklist summary:

Findings:

- AFP results within 30 days: 93%
- Number of specimens tested: 274
- NPEV isolation rate: 21%
- Isolates confirmed: 97%
- Proficiency test result: 100%
- Operating procedures and practices: 93%

Breakdown of review scores:

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<td>Virus isolation</td>
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<td>Supplies</td>
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SUMMARY AND RECOMMENDATIONS FOR GUIZHOU PROVINCE

Laboratory: Guiyang, Guizhou

Date of Review: 19-20 October 1997

Reviewers: Dr Walter Dowdle
            Dr Zhang Xinglu


SUMMARY

This Laboratory is modestly equipped and funded and housed in outmoded facilities. The staff have met many of these challenges to post a considerable improvement in performance over the past year. Although the Laboratory meets all six criteria for accreditation, there remains further opportunities for improvement.

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. One staff member is scheduled for training in Japan in 1998, but additional training is needed in the use of the computer for laboratory data management and analysis.
3. A new inverted microscope should be purchased or the present instrument retrofitted with new light source.
4. A simple box/vial storage system should be initiated to facilitate organization and retrieval of isolates.
5. An inventory system should be established for reagents and supplies to anticipate needs in advance and avoid critical shortages.

Checklist summary:

Findings:
- AFP results within 30 days: 94%
- Number of specimens tested: 540
- NPEV isolation rate: 15.2%
- Isolates confirmed: 96%
- Proficiency test result: 100%
- Operating procedures and practices: 85%

Breakdown of review scores:
- Space: 2
- Staff: 4
- Supervision: 4
- Cell lines: 13
- Stool specimens: 14
- Virus isolation: 15
- Virus identification: 12
- Biosafety: 8
- Cooperation: 10
- Equipment: 1
- Supplies: 2
SUMMARY AND RECOMMENDATIONS FOR ANHUI PROVINCE

Laboratory: Hefei, Anhui

Date of Review: 14-15 October 1997

Reviewers: Dr S. Oberste
Ms Li Jie


SUMMARY

Staff:
There are 2 technical staff in addition to the lab supervisor. The supervisor and both technicians have worked together for 8 years, have 8 years polio lab experience, and have participated in the NPL training course. The supervisor has a good understanding of all procedures and of the programme as a whole.

Equipment and supplies:
The lab space is adequate, all contiguous, and adjacent to the epidemiology space. The lab is well organized, with clear distinction between clean and dirty areas. Their space was recently repaired and painted. Open lab windows in the cell culture room are a potential problem. All required equipment is on hand, much recently purchased by international agencies. Distilled/deionized water is centrally supplied. Glassware is available from central supply and all readily available. Supply stocks are available and well organized. Glass bottles are used instead of TC flasks. The lab is aware of the danger of cell inhibition by detergent residue, so they wash all TC bottles themselves and rinse thoroughly.

Procedures: A large number of specimens were tested in addition to AFP specimens, due to a stool survey of healthy children. Both RD and Hep-2c cells are available weekly for inoculation. Cells are passed only 11 passages before replacement with fresh cells from liquid nitrogen. Each technician processes a specimen from beginning to end, performing stool preparation, inoculation, and typing. All protocols are posted in the lab and also available in a central location. They check temperatures on incubators, freezers, etc., but readings are not recorded.

Biosafety: All safety procedures are observed.

Coordination: The lab and epidemiology staffs interact daily. The lab supervisor and chief epidemiologist share an office and have a good working relationship.

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998,
2. A proportion of NPEV isolates and negatives should be sent to NPL for confirmation.
3. Daily temperature readings should be recorded.
4. Staff could benefit from additional training in equipment use and routine maintenance.
Annex 21

Checklist summary:

Findings:
- AFP results within 30 days: 95%
- Number of specimens tested: 1827
- NPEV isolation rate: 17%
- Isolates confirmed: 92%
- Proficiency test result: 100%
- Operating procedures and practices: 93%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 15
- Stool specimens: 15
- Virus isolation: 14
- Virus identification: 13
- Biosafety: 8
- Cooperation: 10
- Equipment: 3
- Supplies: 3
SUMMARY AND RECOMMENDATIONS FOR FUJIAN PROVINCE

Laboratory: Fuzhou, Fujian

Date of Review: 16-17 October 1997

Reviewers: Dr. S. Oberste
Ms Li Jie


SUMMARY

Staff: The lab staff are young but they have had extramural training and appear to know their jobs. They are also well supervised.

Equipment and supplies: Space is adequate. They lack several pieces of major equipment, including a refrigerated centrifuge, heated stir plate, liquid nitrogen storage system, and sufficient quantity of pipetors. The alarm on their clean bench sounds when in use; water distiller and deionizer are inadequate. They are unable to reset the temperature on their CO₂ incubator.

Procedures: Cells are prepared personally by Dr. He, the lab supervisor, and both RD and Hep-2c cells are available daily for inoculation, resulting in a very short lag time between receipt of specimen and inoculation. Cells are passed only 11 passages before replacement with fresh cells from liquid nitrogen. Each technician processes a specimen from beginning to end, performing stool preparation, inoculation, and typing. All protocols are posted in the lab and also available in a central location. They check temperatures on incubators, freezers, etc., but readings are not recorded.

Biosafety: Lysol, rather than bleach, is used to decontaminate surfaces. Otherwise, safety procedures are followed.

Coordination: They had transport problems which delay the deliver of specimens to the lab from the field. They also identified cold chain problems in poorer areas of the province as an area of programmatic concern. The lab and epidemiology staff occupy adjacent space and interact regularly.
Annex 22

RECOMMENDATIONS

1. The laboratory has met all 6 of the WHO accreditation criteria and should be regarded as a fully accredited laboratory for 1998.
2. Biosafety regulations should be provided and implemented.
3. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures.
4. Retraining and refresher training for laboratory staff, and training in computer data management should be provided.
5. A proportion of NPEV isolates and negatives should be sent to NPL for confirmation.
6. Support should be sought to supply missing equipment.
7. Daily temperature readings should be recorded.

Checklist summary:

Findings:
- AFP results within 30 days: 97%
- Number of specimens tested: 205
- NPEV isolation rate: 18%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 91%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 15
- Stool specimens: 14
- Virus isolation: 14
- Virus identification: 14
- Biosafety: 9
- Cooperation: 9
- Equipment: 1
- Supplies: 3
SUMMARY AND RECOMMENDATIONS FOR HUNAN PROVINCE

Laboratory: Changsha, Hunan
Date of Review: 18-20 October 1997
Reviewers: Dr. S. Oberste
Ms Li Jie
Review outcome: Provisionally accredited for 1998; review performance after 6 months

SUMMARY

Staff: The lab has four full-time and 2 part-time staff, in addition to the lab supervisor. The staff have 3-11 years of experience with polio and two have had extramural training.

Equipment and supplies: Lack of basic essential equipment and certain supplies is a major obstacle faced by this lab. In particular, their autoclave is not adjustable and may be unsuitable for autoclaving media. Their clean bench may not be suitable for cell culture work. They have only one set of pipettors and no repeating dispenser. One of their freezers is in poor condition. Their water deionizer is unusable due to poor flow. The oven is too small. They need a new clean bench for cell culture so that their class II cabinet can be used for virus work. They also lack sufficient cell culture flasks and tubes.

Procedures: Cells are prepared personally by Dr. Zhang, the lab supervisor, and both RD and Hep-2c cells are available for inoculation twice weekly. Cells are passed 20 passages before replacement with fresh cells from liquid nitrogen. Two technicians are responsible for inoculation and two perform polio typing. Protocols are available in a central location and appear to be followed. Stool extracts are prepared on an open bench. Inoculations and typing are also performed on an open lab bench, due to lack of a suitable clean bench for cell culture. They check temperatures on incubators, freezers, etc., but readings are not recorded.

Biosafety: Stool extracts, inoculations, virus typing, etc. are all performed outside of a BSC. Inoculations and typing are performed in a separate "virus room." The staff were initially resistant to the recommendation that virus work must be performed in a class II BSC. Bleach is used to decontaminate pipets, etc., but K₂MnO₄ is used to decontaminate surfaces. Disposable waste is decontaminated with bleach because their autoclave is too small.

Coordination: The lab staff work closely with the epidemiologists.
Annex 23

RECOMMENDATIONS

This lab meets minimum criteria, but needs significant additional help to maintain and improve their performance. The lack of essential equipment is a serious impediment to the performance of this lab.

1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as provisionally accredited,
2. Retraining on current WHO-recommended procedures should be provided as a matter of urgency.
3. Support should be sought for the provision of a tissue culture clean bench.
4. Record keeping for cell passage histories and storage of cells in liquid nitrogen should be improved,
5. Biosafety regulations should be provided and implemented,
6. Recommend sending a proportion of NPEV isolates and negatives to NPL for confirmation.
7. Daily temperature readings should be recorded.
8. The laboratory should be visited again for review after 6 months and its performance re-assessed for accreditation.

Checklist summary:

Findings:
- AFP results within 30 days: 82%
- Number of specimens tested: 559
- NPEV isolation rate: 24.5%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 80%

Breakdown of review scores:
- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 14
- Stool specimens: 14
- Virus isolation: 13
- Virus identification: 13
- Biosafety: 2
- Cooperation: 9
- Equipment: 1
- Supplies: 2
SUMMARY AND RECOMMENDATIONS FOR GANSU PROVINCE

Laboratory: Lanzhou, Gansu

Date of Review: 15-16 October 1997

Reviewers: Ms K.A. Brussen
           Dr J. Wing
           Ms Chai Feng

Review outcome: Provisionally accredited for 1998; review performance after 6 months

SUMMARY

Staff levels appear adequate with only one staff member who has had no extramural training. The majority of lab equipment is available and well located within the laboratory, while clean and dirty areas are well defined. The storage of media/reagents/isolates are not well defined and labelling was incomplete. Regular maintenance is not done and records of critical equipment are not kept. Biohazard cabinet 11 needs regular maintenance, no filter available. The centrifuge was dirty as the 50ml tubes are leaking.

The WHO tissue culture passaging technique is not being strictly adhered to. Records show that specimen processing, virus isolation and typing techniques appear adequate. Rdcc cells are not remaining healthy while Hep2c are being maintained for a number of weeks. Cells are split on an open bench. They have a hanging class 1 that could possibly be modified.

Wild virus is kept in a tape sealed box inside the door of the main lab.

Biosafety practices are in place. There is an obvious close relationship with EPI.

Recommendations

1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as provisionally accredited,
2. Retraining on current WHO-recommended procedures should be provided as a matter of urgency.
3. Support should be sought for the provision of a biological safety cabinet and a new refrigerated centrifuge
4. Wild poliovirus isolates should be stored in a locked box according to current guidelines
5. Record keeping for cell passage histories and storage of cells in liquid nitrogen should be improved,
6. Biosafety regulations should be provided and implemented,
7. Inventories of reagents and poliovirus typing antisera should be established and maintained,
8. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures,
9. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.
Annex 24

Checklist summary:

Findings:
- AFP results within 30 days: 91%
- Number of specimens tested: 481
- NPEV isolation rate: 5%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 80%

Breakdown of review scores:
- Space: 3
- Staff: 3
- Supervision: 4
- Cell lines: 7
- Stool specimens: 14
- Virus isolation: 13
- Virus identification: 12
- Biosafety: 8
- Cooperation: 10
- Equipment: 2
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR QINGHAI PROVINCE

Laboratory: Xining, Qinghai

Date of Review: 17-18 October 1997

Reviewers: Ms K.A. Brussen
Dr J. Wing
Ms Chai Feng

Review outcome: Not accredited for 1998

SUMMARY

Staff is adequate for routine work with extra staff available if lab becomes busy. Most of the essential WHO equipment is available but there is no dedicated CO2 incubator. Glassware appears minimal with no clean stocks available. No records kept of critical equipment or maintenance of equipment. Biosafety Cabinet II no pressure registered when turned on. A spare filter was available. Equipment is well placed between clean and dirty areas with media/reagents/isolates stored in appropriate area but labelling was inadequate.

Both RdCDc and Hep 2c cells are in use with Hep cells remaining healthy for up to 5 days but RdCDc for only 3 days. This could be the seeding level, media or more likely mycoplasma, as new cells from liquid nitrogen only last 2-3 passages before starting to strip.

AFP samples are below the required level. A survey of healthy children has increased the number of samples to the required level. Appropriate specimen processing, virus isolation and typing techniques are in place with full records available. The survey samples are being cultured in tissue culture plates. It is cheaper for the laboratory and it is working well. The lack of healthy cells is of concern with virus isolation and tissue typing.

Biosafety practices are in place. There is no regular meetings with EPI but the staff are helpful when problems arise with AFP cases.

RECOMMENDATIONS

1. The laboratory fails to meet the criteria set by WHO for accreditation and should not be regarded as accredited,
2. Fresh RD and Hep2 cells should be provided
3. Retraining on current WHO-recommended procedures should be provided as a matter of urgency.
4. Location of the tissue culture clean bench and biosafety cabinet should be improved to meet with the requirements of Good Laboratory Practice,
5. Support should be sought for the provision of CO2 incubator,
6. Record keeping for cell passage histories and storage of cells in liquid nitrogen should be improved,
7. Technical supervision from the laboratory supervisor should be improved,
8. Biosafety regulations should be provided and implemented,
9. Coordination between laboratory epidemiology staff should be improved
10. Inventories of reagents and poliovirus typing antisera should be established and maintained,
11. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures.
12. The laboratory should be visited again for review after 6 months and its performance reassessed for accreditation.

Checklist summary:

Findings:
- AFP results within 30 days: 100%
- Number of specimens tested: 254
- NPEV isolation rate: 8%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 76%

Breakdown of review scores:
- Space: 3
- Staff: 2
- Supervision: 2
- Cell lines: 10
- Stool specimens: 14
- Virus isolation: 12
- Virus identification: 13
- Biosafety: 8
- Cooperation: 6
- Equipment: 2
- Supplies: 4
ANNEX 26

SUMMARY AND RECOMMENDATIONS FOR HENAN PROVINCE

Laboratory: Zhengzhou, Henan
Date of Review: 20 October 1997
Reviewers: Ms K.A. Brussen
Ms Chai Feng

SUMMARY

Staff levels and training adequate. A very experienced laboratory. All the essential WHO equipment was available. No regular maintenance or records of critical equipment performed, including Class 2 cabinet. A filter was available. There were well designated clean and dirty areas but media/reagents/isolates were stored in inappropriate areas.

The liquid nitrogen storage system was inappropriate. Labelling of reagents/isolates was incomplete.

Cell culture, virus isolation, and typing techniques followed WHO protocols and full records were available. Specimen processing technique varied slightly from the WHO method but as there is no contamination it is not a problem.

Biosafety protocols in place. There is a very good relationship with EPI.

Wild virus stored in racks in a -70°C freezer. The freezer was locked.

Recommendations.

1. The laboratory meets all of the 6 criteria set by WHO for accreditation and should be regarded as accredited for 1998,
2. Retraining on current WHO-recommended procedures should be provided,
3. Support should be sought for the provision of a standard incubator, CO₂ incubator, and accessory supplies needed to install the distilling apparatus,
4. Record keeping for cell passage histories and storage of cells in liquid nitrogen should be improved,
5. Biosafety regulations should be provided and implemented,
6. Cooperation between laboratory and epidemiology staff should be improved
7. Inventories of reagents and poliovirus typing antisera should be established and maintained,
8. Equipment service manuals should be made available in Chinese and laboratory and the equipment maintenance department should be provided training in installation and maintenance procedures,
Annex 26

Checklist summary:

Findings:
- AFP results within 30 days: 100%
- Number of specimens tested: 2277
- NPEV isolation rate: 13%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 88%

Breakdown of review scores:
- Space: 2
- Staff: 4
- Supervision: 4
- Cell lines: 12
- Stool specimens: 13
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 8
- Cooperation: 9
- Equipment: 2
- Supplies: 4
SUMMARY AND RECOMMENDATIONS FOR SHANDONG PROVINCE

Laboratory: Jinan, Shandong
Date of Review: 14-15 October 1997
Reviewers: Dr R Sanders
Dr Zhang Li Bi

SUMMARY

Staff
The laboratory has 4 full-time staff who are well trained and perform at a very high level of competency. There is excellent co-operation between older and younger staff members.

Equipment and supplies.
Laboratory space is more than adequate for requirements, with laboratories well designed for use. Equipment and consumables are supplied by JICA. One of the biohazard Safety Cabinets has been in use for at least 5 years without the HEPA filter being replaced.

Procedures
a) tissue culture
Tissue culture procedures are excellent and well-documented.

b) isolation and typing
Performance of the laboratory appears to be excellent. The NPEV isolation rate during the preceding 12 months was above 14%. The laboratory processes more than 1200 specimens each year, including more than 400 pooled specimens from AFP contacts.

Biosafety
Staff demonstrated a good comprehension of biosafety procedures, and standard procedures are in place in the laboratory, including the changing of footwear on entry to the laboratory suites.

Coordination
Good cooperation was demonstrated between laboratory staff and epidemiology staff, but coordination of data could be improved. Data held in the laboratory did not exactly match data held by the epidemiologists, which in turn did not match data sent to CAPM in the monthly reports. Laboratory staff receive very little feedback on the data being sent to CAPM, and are never required to check or confirm laboratory data being sent.
Annex 27

RECOMMENDATIONS

1. The laboratory meets the 6 criteria set by WHO for accreditation and should be regarded as an accredited laboratory for the calendar year 1998.
2. Laboratory staff should be given the opportunity to check and confirm laboratory data being sent to CAPM for inclusion in the AFP surveillance database.
3. HEPA filters in the biohazard cabinets should be changed, and support for a replacement refrigerated centrifuge sought.
4. Routine collection and processing of stools from contacts of AFP cases should be stopped in Shandong.

Checklist summary:

Findings:

- AFP results within 30 days: 81%
- Number of specimens tested: 1245
- NPEV isolation rate: 14.2%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 96%

Breakdown of review scores:

- Space: 4
- Staff: 4
- Supervision: 4
- Cell lines: 14
- Stool specimens: 15
- Virus isolation: 15
- Virus identification: 15
- Biosafety: 10
- Cooperation: 9
- Equipment: 3
- Supplies: 3
Summary and Recommendations for Shanghai

Laboratory: Shanghai

Date of Review: 17-18 October 1997

Reviewers: Dr. R. Sanders
Dr. Zhang Li Bi


Summary

Staff
The laboratory has 3 full-time staff, none of whom have received training outside of China.

Equipment and supplies
The laboratory has adequate space and the layout meets the requirements of good laboratory practice, although the clean and dirty areas were only separated during the past year. Equipment is sufficient for requirements, all is functional but most is now old.

Procedures
a) tissue culture
Tissue culture proficiency appears to be good, although the laboratory has problems growing and maintaining good quality RD cells. Cell sensitivity of both RD and Hep2 cells appears to be adequate.

b) isolation and typing
General performance of the laboratory appears to be good. The NPEV isolation rate for the 12 months reviewed was 8.3%, but marked seasonal variation has been recorded. Shanghai has a high economic status, and hygienic conditions are significantly higher than in most other parts of China. In recent years it has been uncommon to isolate NPEV outside of the rainy season months of June to August. The NPEV isolation rate for these three months in 1996 the isolation rate was 32%, and for the same months in 1997 was 33%. Comprehensive line-listings are maintained on all specimens received and processed, but laboratory numbers, not AFP case identification numbers are used in all records.

Biosafety
Staff demonstrated a good comprehension of basic biosafety procedures, with hand-washing and standard decontamination procedures in place.

Coordination
Good cooperation was demonstrated between laboratory staff and epidemiology staff, but coordination of data should be improved. Data held in the laboratory did not match data held by the epidemiologists. Laboratory staff receive very little feedback on the data being sent to CAPM, and are never required to check or confirm laboratory data being sent.
Annex 28

RECOMMENDATIONS

1. The laboratory meets the 6 criteria set by WHO for accreditation and should be regarded as an accredited laboratory for the calendar year 1998.

2. Laboratory staff should be given the opportunity to check and confirm laboratory data being sent to CAPM for inclusion in the AFP surveillance database.

3. Laboratory line listings of specimens received and processed should include the AFP case identification numbers.

4. The condition of laboratory equipment should be reviewed and older equipment replaced as appropriate.

Checklist summary:

Findings:

- AFP results within 30 days: 100%
- Number of specimens tested: 275
- NPEV isolation rate: 8.3%
- Isolates confirmed: 80%
- Proficiency test result: 100%
- Operating procedures and practices: 84%

Breakdown of review scores:

- Space: 4
- Staff: 3
- Supervision: 4
- Cell lines: 14
- Stool specimens: 14
- Virus isolation: 14
- Virus identification: 14
- Biosafety: 10
- Cooperation: 8
- Equipment: 4
- Supplies: 3
SUMMARY AND RECOMMENDATIONS FOR JIANGSU PROVINCE

Laboratory: Nanjing, Jiangsu
Date of Review: 19-20 October 1997
Reviewers: Dr R. Sanders
Dr Zhang Li Bi

SUMMARY

Staff
The laboratory has 3 full-time staff, but only 2 work on specimens from the AFP surveillance system. The other staff member works exclusively on specimens from stool surveys, and works entirely independently of the other two staff members, maintaining his own cells and making his own media and reagents. The two staff working on AFP specimens are both very competent, with many years experience.

Equipment and supplies
The laboratory has adequate space, although the clean and dirty areas were only separated during the past year. A new suit of laboratories has been assigned for use by the polio laboratory, but the layout is less than optimal for a microbiology laboratory. Areas for tissue culture preparation and specimen inoculation are separate, but linked by an adjoining door.

Procedures
a) tissue culture
Tissue culture proficiency appears to be good, with good quality RD and Hep2 cells available.

b) isolation and typing
General performance of the laboratory appears to be good, although record keeping and general documentation could be improved. The workload is high for two staff members. The laboratory experience some difficulties in typing isolates during 1996, when supplies of RIVM typing antisera were exhausted and not replaced. Only 1 isolate has been confirmed by the National laboratory for the 12 months under review, with another isolate pending confirmation in the National Laboratory and two recent isolates awaiting transport to Beijing. Comprehensive line-listings are maintained on all specimens received and processed, but laboratory numbers, not AFP case identification numbers are used in all records.

Biosafety
Staff demonstrated a good comprehension of basic biosafety procedures, with hand-washing and standard decontamination procedures in place.
Coordination

Good cooperation was demonstrated between laboratory staff and epidemiology staff, but coordination of data should be improved. Data held in the laboratory did not match data held by the epidemiologists. Laboratory staff receive very little feedback on the data being sent to CAPM, and are never required to check or confirm laboratory data being sent.

RECOMMENDATIONS

1. The laboratory meets the 6 criteria set by WHO for accreditation and should be regarded as an accredited laboratory for the calendar year 1998.
2. Modifications should be made to the layout of the tissue culture preparation and specimen inoculation areas to provide a clean corridor to separate the two.
3. An additional staff member should be provided to work on specimens generated by the AFP surveillance system.
4. Laboratory staff should be given the opportunity to check and confirm laboratory data being sent to CAPM for inclusion in the AFP surveillance database.
5. Laboratory line listings of specimens received and processed should include the AFP case identification numbers.

Checklist summary:

Findings:

- AFP results within 30 days: 83%
- Number of specimens tested: 510
- NPEV isolation rate: 16.2%
- Isolates confirmed: 100%
- Proficiency test result: 100%
- Operating procedures and practices: 88%

Breakdown of review scores:

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