ANNEX - B

ACCREDITATION CRITERIA FOR CYTOLOGY LABORATORIES FOR EXAMINATION AND TRAINING (Revised2015)

The cytology laboratory must fulfill the following criteria:

1. Status

a) The cytology laboratory should be a division or part of the department of pathology.

OR

- b) Independent Institute / Centre / Department involved in research, training and service aspects of cytology.
- c) The cytology laboratory may be accredited into either of the following categories:
- i) Comprehensive cytology lab / centre
- ii) Gynaecological cytology lab / centre
- iii) Non-gynaecological cytology lab / centre

2. Work load

It should be actively involved in routine cytological work and training and conducting research. The minimum number of cases examined should be 10000 per year. Out of this at least 3,000 cases should be studied for aspiration cytology (for the comprehensive category) with adequate cyto/histo/bacteriological correlation and follow up.

3. **Staff**

Four technicians, one receptionist for the receipt of the specimen and at least one data entry operator for typing the reports. It should have at least two cytopathologist / pathologist, with experience in cytology and adequate infrastructural laboratory staff (technical / others) for its efficient functioning.

4. Adequacy

The laboratory in its report on every case should document the possible inadequacy of the specimens preparation (such as improper preparation or poor fixation) or inadequacies of clinical information. It is suggested that minimum information shall include anatomic site of preparation of every specimen, the age

of patient, previous therapy (endocrine, surgical or radiation), if any, pregnancy status and last menstrual history. (particularly for gynaecological cytology)

5. Rescreening of specimens and diagnostic verifications

The pathologist , cytopathologist or gynaecologist shall rescreen for proper staining and correct diagnostic interpretation, at least 10 percent random samples of cytological specimens from the female reproductive tract which has been interpreted as benign by cytoscreener / resident doctors cytotechnician or cytotechnologist, at least 15 percent of the cytologic preparation from anatomic sites other than the female genital tract interpreted as negative by the cytotechnicians or cytotechnologist; all suspicious and positive smears from the female reproductive tract, all non gynaecological cytology from asymptomatic cases. All the cytological preparation from the anatomic site other than female genital tract be reported upon by the pathologist.

6. Follow - up

The Cytology Laboratory would make an earnest effort to maintain adequate follow-up information of all suspicious and positive smears.

7. Progress / performance Reports

Progress reports shall be prepared by cytology laboratory preferably annually to include number of cases screened in each category, origin of smears, corroborating follow up data and discrepancies, if any, between clinical data, tissue sections and cytologic findings. In case an annual report is not possible, a progress report would be required for reassessment by the Indian Academy of Cytologist at the end of three year period. Detailed account regarding the organization and conduction of examination for cytotechnologists and cytotechnicians should also be included.

8. Slide file

The cytology laboratory shall retain all cytological specimens for at least five years from the date of examination.

9. Education

Since continuing education is essential for quality control, the laboratory shall be required to provide regularly scheduled educational sessions for the benefit of the staff members. A minimum of two hour per week should be devoted to continuing education of the staff members. This should be in addition to the formal curricula as laid down.

10. **Library facilities**

Must have internet access. Departmental library, central library information be provided giving list of books and journals in cytology, pathology and allied subjects.

- 11. Accreditation of the cytology laboratory for examination purpose should also be on the basis of the visitation / inspection as is being done in the cases of accreditation of cytology laboratories for diagnostic service. The criteria laid down should be strictly adhered to.
- 12. The possibilities of recognizing a group of 2-3 centres for imparting group educational activity for training and examination be identified in various regions which could together impact comprehensive training in the regions.
- 13. Accreditation of the cytology laboratory / institute for diagnostic service should not automatically entitle the concerned laboratory / institute to qualify for accreditation for examination purposes.
- 14. ₹10,000/- as fee for accreditation (Laboratories already accreditated for diagnostic purpose shall not have to pay any additional fee when applying for accreditation for examination and training).
- 15. ₹8,000/- for revisitation.