

NABL 111



**National Accreditation Board for
Testing and Calibration Laboratories
(NABL)**

**Procedure for Recognition of Sample Collection Centre/ Facility
declared by Medical Laboratories (CABs)**

**ISSUE NO. : 01
ISSUE DATE : 20-Jun-2018**

**AMENDMENT NO. : 01
AMENDMENT DATE : 24-Jan-2024**

AMENDMENT SHEET

Sl.	Amd. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	03, 04, 05, 06 & 07	----	23.01.2024	As highlighted	Internal review	-Sd/-	-Sd/-
2.								
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1. PROCEDURE

NABL recognizes sample collection centres/ facility (ies) declared by its associated medical CABs. Assessment process of SCFs shall be an ongoing activity for the entire accreditation cycle. Each declared sample collection centre/ facility (SCF) of a medical CAB can be assessed in its accreditation cycle, to the extent possible.

SCFs of applicant CABs

SCFs shall be assessed on sample basis (at least 5%) initially on or before the schedule of initial or renewal assessment and decision shall be taken for all declared SCFs with the assessment report of CAB declaring these SCFs. All declared SCFs shall be considered recognised SCFs of CAB based on the assessment report of the assessed SCFs.

(Refer Flow-diagram).

SCFs of accredited CABs

All declared SCFs not assessed during initial assessment or reassessment can be assessed in subsequent months of accreditation cycle to the extent possible. At all time, the SCFs shall maintain compliance to requirements of NABL and recognition of SCFs is co-terminus with the accreditation cycle of CAB. (Refer Flow-diagram).

Digitalisation of Process

Mobile & Web based Applications has been developed to ease the application process, assessment process, corrective action, and recognition. These applications have provision for CABs to upload details of sample collection centres/facilities for which recognition is to be done, provision for assessor to conduct assessment and for NABL users to assign assessors to these SCFs and review the assessment report. The mobile application will facilitate field assessment, marking location of assessors and laboratories/SCFs. Further, it will involve geo-tagging of sample collection centres/facilities which will help the CAB user/ patients to find these facilities to get quality services. The web-based application can be accessed from NABL website.

Web based Application: Key features

- Manage laboratory, Sample collection centre/facility details and Assessor Data.
- Map based and Dashboard based view of data of laboratories
- Review of Assessment data of sample collection centres.
- Upload corrective actions and follow-up action to close the non-conformities, if any.
- User Management to provide access to different modules.

Mobile application for on-site assessment of collection centres: Key features

- Facility for Collection centre and Assessors to update their profile and mark their location.
- Questionnaire-based Assessment of collection centres along with pictorial evidence.
- Provision to raise non-compliances.


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Recognition of Sample Collection Centre/ Facility

NABL shall issue an annexure along with the accreditation certificate of the CAB containing 'Recognised sample collection centres/ facilities' with the following details –

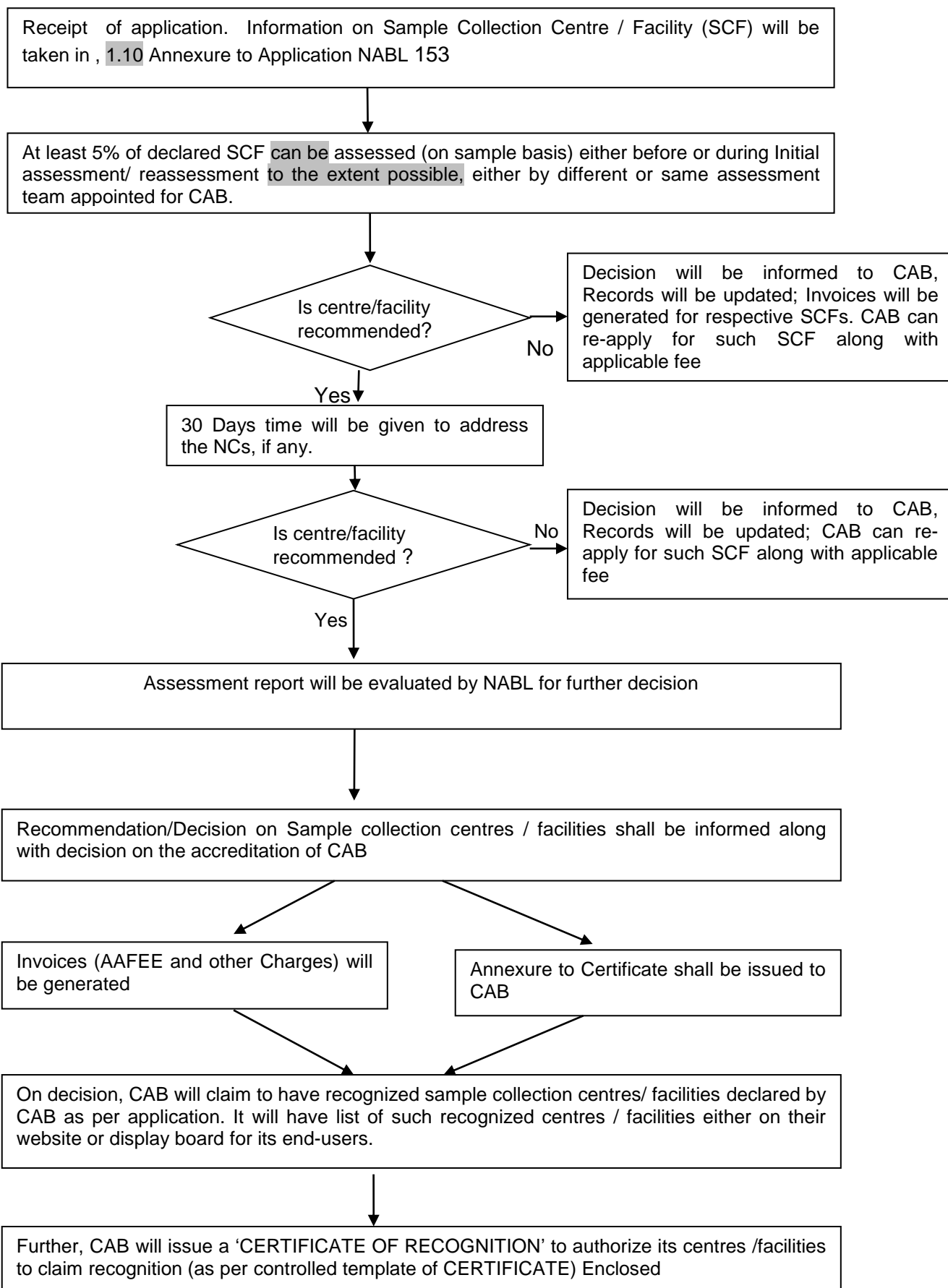
ID of Sample Collection Centre/ Facility	Name of Sample Collection Centre/ Facility	Address of Sample Collection Centre/ Facility
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Based on this annexure, the accredited medical CAB may issue certificate of recognition to its declared SCFs as stated follows –

<i>To be printed on the CAB Letter head</i>	
 MC-XXXX	
<u>CERTIFICATE OF RECOGNITION</u>	
<p>ABC SCF, ADDRESS is a recognized Sample Collection centre/ Facility of XYZ laboratory with certificate no. MC-XXXX and validity (Issue date 00/00/0000 - Valid date 00/00/0000) and is authorized to collect, prepare, handle, transport patient sample collected for this laboratory</p>	
Name and Signature (Signature of Laboratory Director)	Date

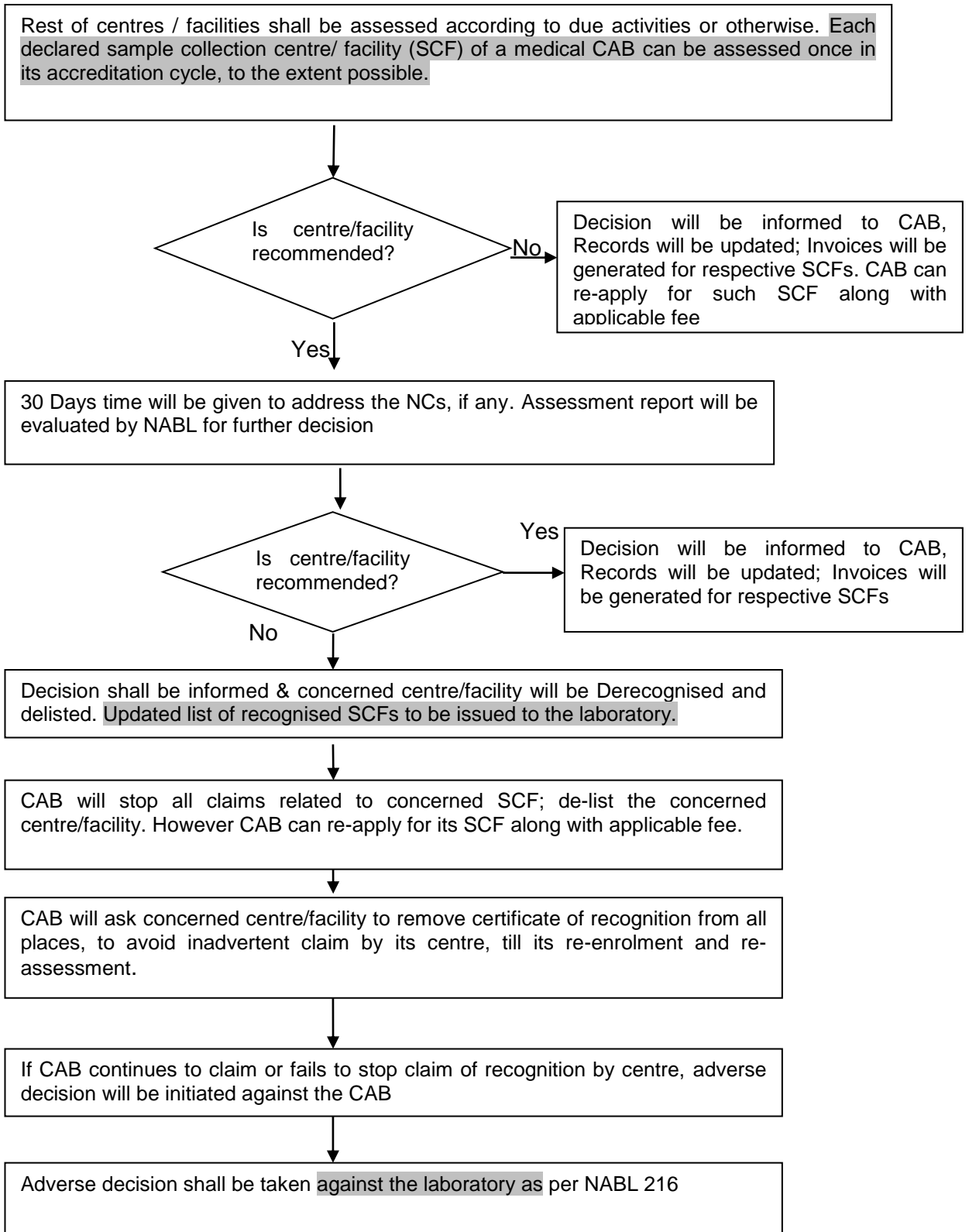
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2. Flow-diagram (Applicant CABs-Initial Assessment/ Reassessment)



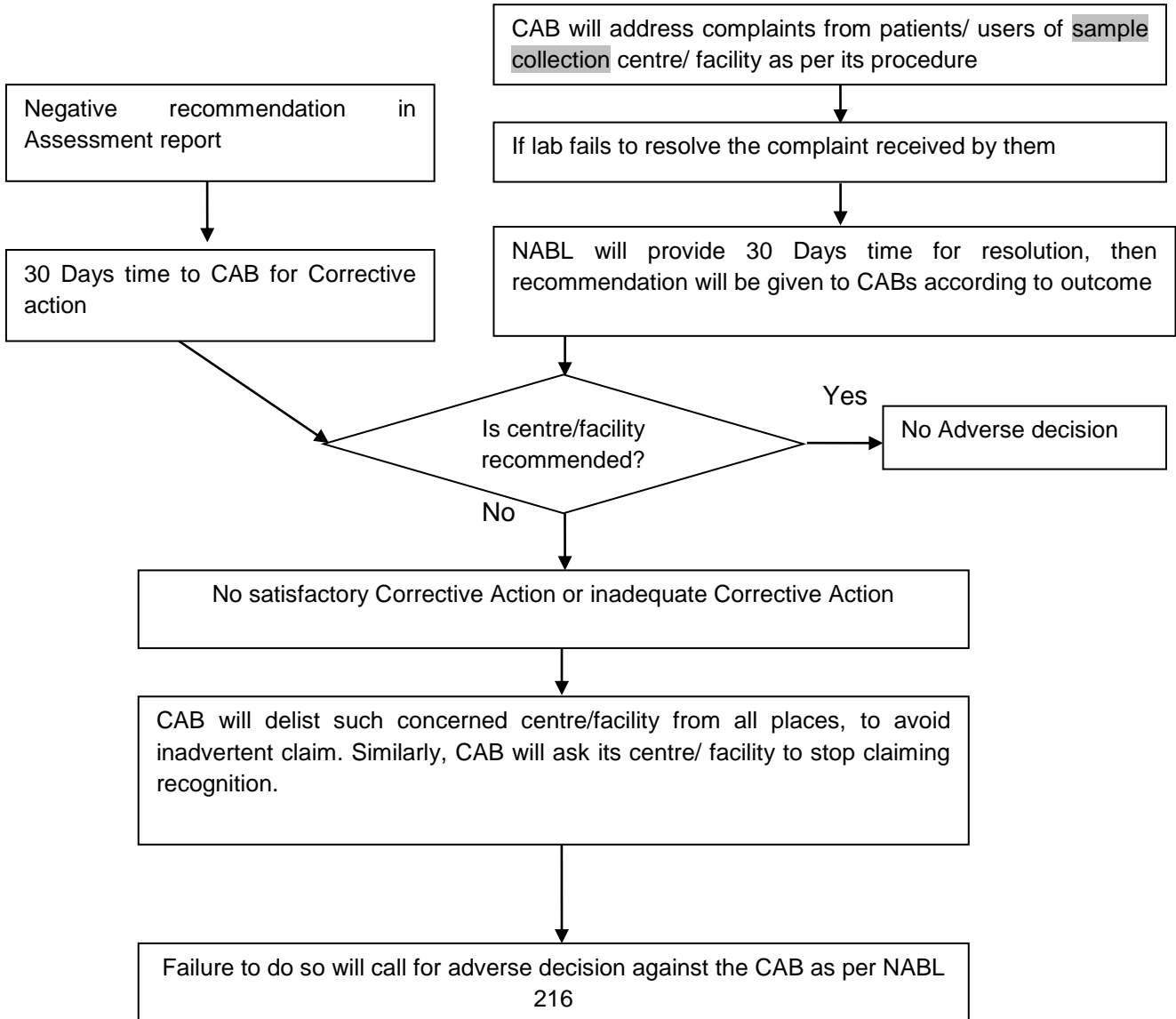
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3. Flow-diagram (Accredited CABs)



4. Adverse decision

When lab is not able to close the issues of complaints pertaining to SCFs and not taking corrective action on the NCs after initial recognition, the CAB shall stop **claim of NABL recognition** or use of NABL symbol for concerned SCFs and return its original annexure. NABL shall issue revised annexure to the medical CAB for other SCFs. Lab shall de-list such concerned centre/ facility from all places, to avoid inadvertent claim. Similarly, lab will ask its centre/ facility to stop claiming recognition.



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