

भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS	CHECKLIST FOR AUDIT OF BRANCH OFFICES (PRODUCT CERTIFICATION) (Clause 3.5, Operating Manual for Product Certification)	CE	2
1. WORKING DOCUMENTS		Check availability of	
<ul style="list-style-type: none"> • Certification Manual & Amendments with each officer 			
<ul style="list-style-type: none"> • CM Proforma Manual and Proformae in use 			
<ul style="list-style-type: none"> • IS Wise Policy Files - Identification sequence wise <ul style="list-style-type: none"> - Latest STIs - Latest Marking Fee Rates 			
<ul style="list-style-type: none"> • Enforcement Manual 			
<ul style="list-style-type: none"> • Quality Control Orders 			
<ul style="list-style-type: none"> • Manual on Preventive Vigilance 			
<ul style="list-style-type: none"> • System of maintaining upto date reference standards 			
<ul style="list-style-type: none"> • List of Approved outside testing laboratories 			
<ul style="list-style-type: none"> • List of Testing Charges 			
2. FILING SYSTEMS & RECORDS		Check whether adequate systems developed for	
<ul style="list-style-type: none"> • Indexing of files and registers 			
<ul style="list-style-type: none"> • Orderly storage of records 			
<ul style="list-style-type: none"> • Sequential filing of papers, page numbering 			
<ul style="list-style-type: none"> • Safe and proper physical maintenance of records 			
<ul style="list-style-type: none"> • Issue control of CM Proformae 			
<ul style="list-style-type: none"> • Retention, storage of old files, weeding out etc 			
		Check whether these records are being maintained	
<ul style="list-style-type: none"> • CM/PF 303 Register of Applications for Licence to use Standard Mark 			
<ul style="list-style-type: none"> • CM/PF 401 Record of samples procured by ROs/BOs for Testing 			
<ul style="list-style-type: none"> • CM/PF 601 Register of Licences for the use of the Standard Mark 			
3. RESPONSIBILITY & AUTHORITY		Check implementation of	
<ul style="list-style-type: none"> • Allocation of work is documented and responsibilities of Dealing Officer, Group Leaders, Section Officer, Certification Staff are clearly defined (3.2.2 & others) 			
<ul style="list-style-type: none"> • Authority as specified in the Manual is being exercised correctly with particular reference to: <ul style="list-style-type: none"> ○ Rejection of applications (2.2.7) ○ Factory testing of samples for Grant of Licence (2.9.5) ○ Review of Inspection Reports (3.7.3) ○ Intimation for Grant of Licence (2.9.8) ○ Factory testing for inclusion of new variety (2.10.3) ○ Supervisory Inspections (3.4) ○ Drawl of market samples of other BOs [3.8.4(a)] ○ Receipt of Test Reports by Group Leader / Officer (3.9.1) ○ Testing of Counter Samples (3.9.3) ○ Testing of duplicate samples in another lab (3.9.4) ○ Approval for criticality of failure (3.9.7) ○ Follow up actions including stop marking (3.11) ○ Imposition of Stop Marking (3.11.2.3, 3.11.2.1 Notes 1 & 2) ○ Resumption of Stop Marking (3.11.2.4 ii) ○ Recommendation / Orders on Blue Forms (3.12.2, 3.12.3, 3.12.6, 3.12.6.1) ○ Endorsement in licences (3.12.5) ○ Renewal of deferred licences (3.12.8 Note 2) 			

<ul style="list-style-type: none"> ○ Issue of cancellation notice (3.12.9.1) ○ Permission to mark as per old standard (4.6.5.3) ○ Factory testing for implementation of Amendment (4.6.7) 	
<p>4. CONFIDENTIALITY & IMPARTIALITY</p>	<p>Check whether</p>
<ul style="list-style-type: none"> • Procedure or otherwise a protocol exists for receiving visitors 	
<ul style="list-style-type: none"> • Any specific actions taken to discourage undue interaction of applicants / licensees with staff etc. 	
<ul style="list-style-type: none"> • Systems exist to maintain confidentiality in respect of <ul style="list-style-type: none"> ○ Certification files (information therein) ○ Test Reports – coding, decoding and movement to concerned persons 	
<ul style="list-style-type: none"> • Cases are disposed off in non-discriminatory manner in respect of <ul style="list-style-type: none"> ○ Closure of applications ○ Processing of Red Forms ○ Renewals ○ Stop marking and resumptions ○ Cancellation of licences 	
<ul style="list-style-type: none"> • Uniformity exists in reporting, review and decisions 	
<p>5. PROCESSING OF APPLICATIONS (Sample 5% from pending applications, licences granted and applications closed during last one year)</p>	<p>Examine these</p>
<ul style="list-style-type: none"> • Whether procedure outlined in respect of receipt, scrutiny, recording, return and rejection of applications has been followed (2.2.1 to 2.2.5) 	
<ul style="list-style-type: none"> • Whether procedure and time norms for processing, rejection or retention of applications has been followed (2.2.7 & 2.3.1.1) 	
<ul style="list-style-type: none"> • Preliminary inspection report is complete in all respects particularly: <ul style="list-style-type: none"> ○ Verification methods for raw materials specified in ISS/STI ○ Description of manufacturing process and controls ○ Final product inspection and tests ○ Competence of testing personnel ○ Factory test report ○ Verification of Plant Machinery & Test Equipment (PF 305 & PF 306) ○ Acceptances of STI, Marking Fee, Declaration of Brand Names ○ Discrepancy / Variations observed ○ Inspecting Officer's assessment of capability of applicant to operate the scheme (2.7.3) ○ Validity of recommendation vis-à-vis manufacturing capability, testing capability, representative samples drawn for IT. 	
<ul style="list-style-type: none"> • Whether Preliminary Inspection Report has been reviewed 	
<ul style="list-style-type: none"> • Whether all pending actions are verified and reported in follow up inspection reports 	
<ul style="list-style-type: none"> • Whether Test Reports are complete, assessed correctly and conformity status recorded 	
<ul style="list-style-type: none"> • Whether efforts have been made to process the application with specified time norms (2.2.6 & 2.3.1.1) 	
<ul style="list-style-type: none"> • Whether confirmatory samples have been drawn for long duration tests (2.9 Note 2) 	
<ul style="list-style-type: none"> • Whether information in Red Form is accurate and correct 	
<ul style="list-style-type: none"> • Whether actions on Referred back Red Form have been taken expeditiously 	
<ul style="list-style-type: none"> • Whether timely actions were taken after grant of licence (2.9.3) 	
<p>6. OPERATION OF LICENCES (Sample 5 % of operative licences, licenses lapses / cancelled in last one year)</p>	<p>Examine whether</p>
<ul style="list-style-type: none"> • A minimum of two inspections have been carried out in an operative year 	
<ul style="list-style-type: none"> • Periodic Inspection Reports are submitted timely and are complete with particular referenc <ul style="list-style-type: none"> ○ Verification of corrective actions, other pending actions ○ Raw material tests and controls ○ Recording of Production and Marking details ○ Significant changes in licensee's set up ○ Factory test results & corresponding factory records ○ Details of samples drawn together with declared values and corresponding factory records 	

<ul style="list-style-type: none"> ○ Discrepancy / Variation Report and agreed actions are clear and signed by the IO and Firm's representative 	
<ul style="list-style-type: none"> ● All Inspection Reports have been reviewed 	
<ul style="list-style-type: none"> ● Market samples have been drawn as per norms 	
<ul style="list-style-type: none"> ● Test Reports received in time or reminders issued <ul style="list-style-type: none"> ○ Test reports have been assessed correctly and conformity status recorded (3.9.2) ○ Actions on failures have been taken timely (3.9.7) ○ Follow up actions including Stop Marking have been taken as per procedure ○ Renewal notices has been sent on time ○ Blue Form is complete in all respects including 'Any Other Information' (3.12.4) and at least one meaningful inspection has been carried out (3.3.2) ○ Decision of Renewal / Non Renewal / Deferment of Renewal has been done as per procedure (3.12.4) ○ Cases falling under 3.12.6 have been referred to DDGR ○ Deferment / Stop marking period has been exceeded specified time limits ○ Action for cancellation initiated as per 3.12.9 and cancellation notice has been issued to DDGR ○ Endorsements to licences have been issued correctly and timely ○ Appropriate actions taken following changes in structure of licensee (4.6.1) ○ Revisions / amendments to standards & STI have been implemented from the assigned date. ○ Inclusion of Additional varieties has been done as per procedure (2.10.3) 	
7. MONITORING SYSTEMS	Check whether the following actions are being taken
<ul style="list-style-type: none"> ● Monthly review of pending applications (2.2.6) 	
<ul style="list-style-type: none"> ● Preparing Quarterly Inspection Programmes (3.2). Check how the programme is monitored at BO level 	
<ul style="list-style-type: none"> ● Supervisory Inspections by Head of BO (3.4) 	
<ul style="list-style-type: none"> ● Review of Performance where ordered by Competent Authority 	
<ul style="list-style-type: none"> ● Monitoring of target for market samples 	
<ul style="list-style-type: none"> ● Organizing licensee Review Meetings as allocated 	
8. HANDLING OF COMPLIANTS (ANNEX 9)	Check whether
<ul style="list-style-type: none"> ● A Complaint Register has been maintained (1.3) 	
<ul style="list-style-type: none"> ● All complaints have been acknowledged (1.1a) 	
<ul style="list-style-type: none"> ● Complaint data sheet has been forwarded to CAD (1.1 d) 	
<ul style="list-style-type: none"> ● Monthly statement is being sent to CAD (1.3) 	
	Check few files to see whether
<ul style="list-style-type: none"> ● Investigations have been done within time norms (2.2) 	
<ul style="list-style-type: none"> ● Complainant and investigation report (Appendix 2) has been sent to Licensee end BO 	
<ul style="list-style-type: none"> ● Licensee end investigation report has been filed separately in Appendix 3 	
<ul style="list-style-type: none"> ● Outcome of investigation has been informed to the complainant or licensee intimated to arrange redressal 	
<ul style="list-style-type: none"> ● Satisfaction letter has been obtained from complainant 	
<ul style="list-style-type: none"> ● Action taken against licensee when compliant is established (3.1 c, h, k) 	
<ul style="list-style-type: none"> ● Closure of compliant has been put up to DDGR (Appendix 2) 	
9. MISCELLANEOUS	Check whether
<ul style="list-style-type: none"> ● Enforcement procedures are being followed as per Enforcement Manual 	
<ul style="list-style-type: none"> ● Legal cases are being followed up regularly 	
<ul style="list-style-type: none"> ● Computer records are being maintained and sent to CMD / IT Services Dept. 	
<ul style="list-style-type: none"> ● Training needs of officers and staff have been communicated to HRD 	