CENTRAL MARKS DEPARTMENT-1

Our Ref: CMD-1/2:1 Date: 01 Dec 2016

Sub: Guidelines on Stoppage of Marking and Resumption of Marking

These guidelines stipulate the procedure for imposition of stop marking, separately on account of failure of samples or unsatisfactory performance or special situations.

A. STOP MARKING AND RESUMPTON OF MARKING IN CASE OF FAILURE OF SAMPLES

Receipt of Test Reports

- 1. Each BO shall maintain a record for independent test reports downloaded from LIMS, or received in the dak. Maintaining the record and delivering the test reports to the concerned dealing officer (DO) shall be the responsibility of the person designated by Head BO.
- 2. The DO shall examine the test reports and record 'Pass/Fail' on it with his signature, name and date. In case of failure of sample, the DO shall record on the test report, the requirements in which the sample has failed and also make necessary entry in CMMS.

Failure of Samples

- 3. When a failure test report is received, the dealing officer shall prepare "Review of Performance" (ROP) wherein he shall determine, in accordance with para 4 & para 5 whether it is a case of **first failure** or **consecutive failure**.
- 4. **First Failure of sample:** The failure of sample in Independent Testing (IT) shall be treated as first failure, if the previous test report (based on date of manufacturing or in its absence date of drawl) is found passing.
- 5. **Consecutive Failure of sample:** Any failure of sample in IT shall be treated as a consecutive sample failure if its date of manufacturing (in case date of manufacturing is not available, then date of drawl) is after the date of completion of corrective actions on 1st failure and there is no 'pass' test report in between.

Note: In case ROM has been done previously and the test report relates to the period prior to ROM, then it will not be considered for the purpose of review. However, failure, if any, shall be communicated to the licensee.

Stop Marking due to failure of samples

- Stop marking shall be imposed in the event of consecutive failure of samples. However,in case of food products failing in the requirement of radioactive residues or pesticides or toxicity, stop marking shall be imposed on first failure itself. The DO shall recommend the case accordingly and put up the ROP to the Head BO.
- 7. In situations other than para 6 above, the failure shall be communicated to the licensee in CM/PF 115(Annex-1) through email/speed post with a

copy of the test report. The licensee shall be advised to take corrective actions and submit its reply along with supporting evidence, as applicable, within 1 month from the date of communication.

- 8. When the corrective actions as mentioned at para 7 above, are received within 1 month, the DO shall put up the case to the Head BO for nominating an officer for verification of the corrective actions within 3 months through a surveillance inspection.
- However, if corrective actions as mentioned at para 7 are not received within 1 month, the case shall be processed for imposition of stop marking.

Communication of Stop Marking

10. The decision of stop marking shall be promptly communicated to the licensee in CM/PF 116 (Annex-2) through email/speed post seeking its response. If response is received, then further action shall be taken as per para 11, 12 and 13. If no response is received within 45 days from the date of communication of stop marking, the licence shall be processed for cancellation.

Inspection for Resumption of Marking (ROM)

11. On receipt of corrective actions, an inspection for considering ROM shall be organized by the Head BO within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded. During the inspection, the IO shall verify the corrective actions taken by the licensee.

If all the requirements in which failure was reported can be tested in the factory in a day, then sample from the lot offered shall be tested in the factory for all possible tests including the requirements in which sample(s) failed.

In case all the requirements in which failure was reported cannot be tested in the factory, then sample shall be drawn for independent testing and got tested for all requirements except the ones for which testing time is more than one month. However, if the failure is in such requirements for which testing time is more than one month, then the sample shall be got tested for these requirements also. The testing charges shall be borne by the licensee.

Processing ROM

12. If the sample passes in FT or IT, as the case may be, ROM shall be processed within 7 days' time.

Failure of sample drawn for ROM

13. If the sample drawn on the first occasion for considering ROM fails in testing (FT or IT, as the case may be), another chance may be given for improvement and reoffering of sample. In such cases, sample shall be drawn for independent testing and ROM will be based on result of such independent testing only.

However, if the sample fails even on the second occasion, the licence shall be processed for cancellation.

Inspection Charges 14. All inspections for considering ROM shall be chargeable as per provisions of OMPC.

B. <u>STOP MARKING AND RESUMPTON OF MARKING IN CASE OF UNSATISFACTORY</u> PERFORMANCE

Unsatisfactory Performance of licence

- 15. Performance of a licence shall be treated as unsatisfactory in case of discrepancies observed in the operation of the licence. Such situations are not limited to, but may include the following:
 - a) Using standard mark on product that is not covered under the licence
 - b) Relocation of plant and machinery to a different address without prior intimation
 - c) Significant modifications in plant, machinery and process without prior evaluation and approval of BIS
 - d) Failure of sample in factory testing
 - e) Marking of products in absence of testing personnel
 - f) Marking of products even when testing equipment is out of order
 - g) Violation of provisions of scheme of testing and inspection including hygienic conditions, where applicable
 - h) Marking of non-conforming products

Inspection report indicating unsatisfactory performance

- 16. In case of unsatisfactory performance, the inspection report along with the DVR shall be submitted by the IO within 7 days from the date of inspection and necessary data entry shall be made by him in CMMS.
- 17. The DO shall prepare Review of Performance (ROP) wherein he shall determine whether it is a case of **first instance** of unsatisfactory performance or **consecutive instances** of unsatisfactory performance.

Stop Marking due to Unsatisfactory Performance

- 18. In case of consecutive instances of unsatisfactory performance, stop marking shall be imposed. However, stop marking is not to be considered on the basis of combination of failure of samples in independent testing and unsatisfactory performance.
 - In case of significant modifications in plant, machinery and process without prior evaluation and approval of BIS as at para 15(c), stop marking shall be imposed at the first instance itself.
- 19. When discrepancies mentioned at para 15 (a) or 15 (b) are noticed, the licence shall be processed for cancellation. The cancellation notice to be issued in CM/PF 118 (Annex-4) shall also include directions for stop marking.

The DO shall recommend the case accordingly and put up the ROP to the Head BO.

- 20. In case of discrepancies mentioned at para 15 (d) to 15 (h), the reasons for unsatisfactory performance shall be communicated to the licensee in CM/PF 117(Annex-3) through email/speed post with a copy of the DV report. The licensee shall be advised to take corrective actions and submit its reply along with supporting evidence, as applicable, within 1 month from the date of communication.
- 21. When the corrective actions are received within 1 month, the DO shall put up the case to the Head BO for nominating an officer for verification of the corrective actions within 3 months through a surveillance inspection.

However, if complete and satisfactory reply along with supporting evidence, if any, is not received within 1 month from the date of communication of unsatisfactory performance, the case shall be processed for imposition of stop marking.

22. The decision of stop marking shall be promptly communicated to the licensee in CM/PF 116 (Annex-2) through email/speed post seeking its response. If response is received, then further action shall be taken as per para 23 and 24. If no response is received within 45 days from the date of communication of stop marking, the licence shall be processed for cancellation.

Inspection for Resumption of Marking (ROM)

- (a) On receipt of corrective actions, an inspection for considering ROM shall be organized by the Head BO within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded. Wherever it is necessary for verification of corrective actions, sample from one lot shall be tested in the factory for all possible tests in a day.
 - (b) In case of stop marking due to significant modifications in plant, machinery and process without prior evaluation and approval of BIS [Para 15(c)], sample shall be drawn for complete independent testing. The testing charges shall be borne by the licensee.

Processing ROM

- 24. (a) The action for ROM shall be completed within three weeks' time from the date of receipt of corrective actions from the licensee. However, if the corrective actions are found to be insufficient, or if the sample fails in factory-testing (where applicable), the licence shall be processed for cancellation.
 - (b)In case of **para 23(b)**, the action for ROM shall be completed within 7 days' time from the date of receipt of test report indicating conformity of the sample. However, if the sample fails in IT, the licence shall be processed for cancellation.

C. STOP MARKING AND RESUMPTON OF MARKING IN CASE OF SPECIAL SITUATIONS

Shifting of premises

25. When a licensee informs about shifting of the manufacturing facilities to a new address, stop marking shall be imposed. The decision on stop

marking shall be communicated to the licensee (CM/PF 116) with an advise to also inform-

- (i) The proposed new address to which the manufacturing facilities are being shifted,
- (ii) Document for authentication of the new premises of manufacture,
- (iii) Location map for the new premises,
- (iv) The probable date for completion of the shifting process.

Inspection for considering ROM

26. On receipt of information from the licensee about completion of shifting process, inspection shall be carried out at the old as well as the new premises to verify the same. During the inspection at the new premises, among other things, the IO shall –

- (a) verify the manufacturing machinery, test equipment, plant layout and, if applicable hygienic conditions and reflect them in the applicable proforma (CM/PF 305, CM/PF 306, hygienic conditions etc.). If QCI has changed, the competence of QCI shall also be checked.
- (b) verify the working condition of the manufacturing machinery and test equipment, and if required, a sample may be subjected to testing to ascertain the workability of manufacturing and testing equipment.
- (c) in case of PDW and PNMW, draw a product sample for complete independent testing including radioactive residues, as change of source of water is involved. The testing charges shall be borne by the licensee.

Processing ROM

27. The process for ROM shall be completed within 3 weeks from the date of receipt of information from the licensee about completeness of the shifting process. However, in case of shifting of premises of PDW and PNMW licences, the process for ROM shall be completed within 7 days from the date of receipt of satisfactory test report. The new address shall be endorsed in the licence.

In case the licence does not confirm completion of shifting process for more than 3 months, a visit may be organized to both the new and existing premises to check any possible misuse of standard mark.

Non-payment of fees, inspection or testing charges

28. In case of non-payment of fees, inspection charges or testing charges, SOM shall be imposed after giving 14 days' notice to the licensee. Resumption of marking shall be considered as soon as the dues are cleared by the licensee.

Revision of Marking fee and

29. In case of revision of marking fee/STI, if the licensee does not submit the acceptance of revised marking fee/revised STI within the stipulated time, the licence shall be processed for cancellation. The cancellation notice shall also include directions for stop marking.

Nonimplementation of revised ISS

- 30. In case of non-implementation of revised ISS, amendment to ISS or revised STI, **SOM shall be imposed**, if-
 - (a) Additional testing facilities with the licensee are required and the licensee fails to develop the facility by the stipulated time;
 - (b) Non-submission of evidence of conformity to the revised provisions where it is a requirement as per the relevant CMD circular;
- 31. In case of SOM as at para 30,
 - (a) Where the licensee has failed to develop the additional testing facilities, ROM shall be permitted on verification of additional testing facility through inspection.
 - (b) Where evidence of conformity to the revised ISS is not available, ROM shall be permitted on receipt of evidence of conformity of the product as per the new provisions.
 - (c) If action for resumption of marking is not taken by the licensee within a maximum period of 3 months, the licence shall be processed for cancellation.

Deferment of renewal

32.

In case of deferment of renewal of a licence, the licensee shall be directed to stop marking his product with standard mark till such time a decision is taken to renew the licence.

Self-stoppage of Marking

33.

- (a) If at any time the licensee finds it difficult to maintain the conformity of the product to the relevant Indian Standard, due to any reason, he may resort to self-stoppage of marking under intimation to BIS. In such cases, he may resume marking after removal of defects, under intimation to BIS.
- (b) In all such cases, the status of the licence shall be updated accordingly in CMMS by the dealing officer, on receipt of the information.
- (c) If the period of self-stoppage of marking exceeds 3 months, a visit may be organized by the Head BO to check any possible misuse of the standard mark.

<u>CM/PF 115</u> December 2016

SPEED-POST/E-MAIL

Our Ref:	ef: Date:		
Subject: Non-conformity of sample p	ertaining to CM/L		
M/s			
Madam/Sir,			
granted to you			
name) manufactured according to IS			
2. In accordance with Regulation 5 sample mentioned below was drawn a standard during independent testing (co	and found not conform	ning to the requirements of the	
Particulars of Sample:			
	ate of Manufacturing: ate of sampling:		
Size/ Variety/ Type/Grade: Source: Factory/Market Sample(purcha	ase details)		
Name of Laboratory	Test Report No	Requirement(s) in which sample failed	

- 3. You are required to investigate the reasons for non-conformity by reviewing your quality assurance system and to take appropriate corrective actions. You may test the improved product after the corrective actions have been taken to ensure that the actions taken are appropriate to prevent recurrence of non-conformities observed.
- 4. You are further required to intimate BIS the details of corrective actions taken along with applicable supporting evidence within 30 days of the issuance of this letter, failing which your case shall be processed for imposition of stop marking. You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS.

- 5. Please note that as per BIS certification Regulation 5(7) (a) the licensee shall stop (self-stoppage) using the Standard Mark on the product as soon as the non-conformity is noticed/communicated. The marking may be resumed by licensee (self resumption) as soon as appropriate actions are taken to rectify the defects and the information about the corrective actions taken is sent so as to reach the Bureau within 30 days from the date of issuance of this letter.
- 6. You are advised to take appropriate action to withdraw the non-conforming material pertaining to the Batch/Lot/C.U number (Ref para 2 above) from market/dealer/distributor under intimation to this office.
- 7. In view of the non-conformity at para 2, above, you are required to retest the available stock and ensure conformity to relevant standard before dispatch. Record of such retesting must be maintained.
- 8. It may also be noted that, the Bureau may impose stop marking according to the provisions of Regulation 5(7)(b) of BIS (Certification) Regulations, 1988 if any other sample (after completion of corrective action) is found not conforming to the standard.
- 9. Kindly acknowledge receipt and ensure compliance and reply as per para 4 above.

Yours faithfully,

Encl: as stated.

^{*} Strike off whichever is not applicable.

CM/PF 116 December 2016

Date:

SPEED-POST/E-MAIL

Our Ref:

of receipt of fax/email.

c) Packing details; and

addresses

a) Quantity of material with Standard Mark held in stock:

Subject: Stop Marking on (product name) under CM/L					
M/s					
(Licensee Name and Address)					
Kind Attn: (Name of the CEO/MD)					
Madam/Sir,					
1. This has reference to the BIS Certification Marks Licence No. CM/Lgranted to you for use of Standard Mark on					
2. In accordance with the provisions of Regulation 5 (7) (b) of BIS (Certification) Regulations, 1988, it has been decided to put your licence under Stop Marking with immediate effect due to the following reason(s):					
3. You are not permitted to mark and dispatch (including stock in hand) the above mentioned product with Standard Mark. You are, therefore, advised to ensure stoppage of marking on the product with immediate effect & confirm the same immediately preferably by return speed post/e-mail. You are also advised to submit us the following details as on the date					

4.Your reply with above stated details must reach us within 15 days of the issuance of this letter failing which it will be presumed that you do not have such material in stock. In case it is subsequently found that you have sold the material with Standard Mark after receipt of BIS instructions to stop marking, it will be construed that the material so sold has been marked subsequently contravening the provisions of Section 11 of BIS Act, 1986. In such an eventuality, the Bureau will reserve the right to take such action against you as envisaged in the BIS Act, 1986, Rules & Regulations framed there under.

d) Pending Orders for material with Standard Mark, if any with purchasers' names and

b) (i) Batch No(s), and date(s) of manufacture; (ii) Brand; (iii) size/type/grade/variety;

- **5.** *You are advised to take appropriate action to withdraw the material pertaining to the non-conforming Batch/Lot/C.U number...... from market /dealer/distributor, wherever possible, under intimation to this office.
- **6.** Kindly note that, according to Regulation 6 of BIS (Certification) Regulations, 1988, the minimum marking fee as indicated in the Second Schedule of above mentioned licence is payable by you even during the period the licence is not in operation due to stoppage of marking.
- 7. You are required to take necessary corrective action in the context of the reasons for stop marking as stated in Para 2 above and submit complete details of compliance with all supporting evidence, as applicable, for examination and verification. *You are advised to produce a fresh batch/lot/control-unit after taking corrective actions and confirm your readiness for the visit by BIS to consider resumption of marking.
- **8.** A sum of Rs. shall be payable to BIS in advance towards this visit.
- 9. The reply with information sought under point 4 & 5 above should be sent immediately by return speed post/e-mail but not later than 15 days from the issuance of this letter. Further, complete reply with respect to Para 7 should reach BIS within 45 days failing which your licence will be considered for expiry/cancellation as per regulation 5(5)(a).
- **9.** Kindly acknowledge receipt and ensure compliance.

Encl. As stated Yours faithfully,

Copy to: Quality Control In-charge (Licensee Name & Address)

^{*} Strike off where not applicable

CM/PF 117 December 2016

SPEED-POST/E-MAIL

Our Ref:		Date:
Subject: Unsatisfactory performance pertaining to CM/	L	
M/s.		
Madam/Sir,		
This has reference to the BIS Certification Marks Licence you for use of Standard Mark on		_
A Surveillance Inspection was carried out at your unit of discrepancies in the operation of the licence were observed D/V report issued during the visit, copy enclosed). You corrective actions to avoid such discrepancies in future and taken along with applicable supporting evidence within 30 contents.	d and communic a are advised to intimate BIS the	cated to you (Ref. take appropriate details of actions
Kindly note that in case, complete/satisfactory reply is reperiod or performance during next surveillance visit is marking may be imposed in accordance with Regulation Regulations, 1988.	also found un	satisfactory, stop
Thanking you		
	Yours fa	nithfully,
	()
Encl: As above		

CM/PF 118 December 2016

SPEED POST/EMAIL

Our	Ref:	BO/L-		Dated:
			ncellation of BIS ((Product Name)	Certification Marks licence No.CM/L
M/s				
(Lic	ensee]	Name and A	ddress)	
			Kind Attn: (Name of the CEO/MD)
Dear	r Sir,		`	,
you as p	1	to use	the Standard	fication Marks Licence No. CM/L held by Mark on your product "" , which is valid up to
2. abov	The licer		rious discrepancies	were observed with regard to the operation of the
	(.	RO/BO to gi	ve the reasons for p	proposed cancellation in this space)
	cellatio	on in accorda	ance with 15 (1) or	to consider the licence CM/L-held by you, fo f BIS Act, 1986 read in conjunction with Regulation, 1988.
there	luding efore, a irm th	stock in har advised to er ae same imn	nd) the above men nsure stoppage of mediately preferable	enceforth, not permitted to mark and dispatch ntioned product with Standard Mark. You are marking on the product with immediate effect & by by returned speed post/e-mail. You are also as on the date of receipt of fax/email.
b) c) d)	(i) Bat Packir	tch No(s). and ng details; and ng Orders fo	d	ark held in stock: cture; (ii) Brand; (iii) size/type/grade/variety; andard Mark, if any with purchasers' names and
5.	In ca	ase you have	anything to say in	this matter, you may submit your explanation to

This notice is being issued without any prejudice to the right of this Bureau to take any legal action under section 33 of BIS Act, 1986.

the Bureau within 14 days from the date of issue of this notice, failing which, it will be presumed that you are no longer interested in continuing the said licence and as such

the licence will be processed for cancellation without any further reference to you.

6. If you desire to be heard in person by the undersigned, you may seek an appointmen for such a hearing with the undersigned, after submitting your written explanation.		
Kindly acknowledge the receipt of this letter.		
Thanking you,		
Yours faithfully,		
() Dy. Director General		
Encl:		
* Strike off where not applicable		