

GUIDELINES FOR GRANT OF LICENCE FOR CONFORMITY ASSESSMENT SCHEME FOR MILK AS PER SCHEME-IX OF BIS (CA) REGULATIONS, 2021

1. Purpose

To ensure that all dairy unit/ organization applying for licence for Conformity Assessment Scheme for Milk and Milk Products meet uniform certification criteria as set out in these guidelines.

2. Scope

This document provides guidance for Grant of licence in accordance with Conformity Assessment Scheme for Milk and Milk Products and shall be read in conjunction with the Scheme-IX of BIS (Conformity Assessment) Regulations (Sixth Amendment), 2021. At present, 34 Milk and Milk Product Indian Standards are available for certification under this scheme. ([Annex-1](#))

3. General Principles for Grant of Licence

The Bureau grants a licence based on successful assessment of the following through visit to the manufacturing premises:

- i) Requirements of Product Certification as per relevant Indian Standard(s);
 - ii) Assessment of Food Safety Management System implemented by the organization as per IS/ISO 22000; and
 - iii) Process requirements as given in [Annex-II](#) of Scheme document.
- This scheme is applicable when above three components are assessed together.

4. Application

The application shall be made in Form-I ([Annex-III](#)) as specified in the BIS (Conformity Assessment) Regulations (Sixth Amendment), 2021 along with relevant documents and fees.

Pre-requisites for a dairy unit to be eligible for applying for certification:

1. The unit shall hold valid Licence from Food Safety and Standards Authority of India (FSSAI) as required under the Food Safety and Standards Act, 2006 and Regulations there under.
2. The unit has established an inspection and testing plan for each product to be covered under the scope of this certification scheme. Wherever Scheme of Inspection and Testing plan has been developed by the Bureau, it is recommended that the same shall be adopted by the manufacturer.
3. The unit has implemented a Food Safety Management System in accordance with IS/ISO 22000.
4. The unit has established process requirements as specified in [Annex-II](#) of this scheme.
5. The milk and milk products are conforming to the relevant Indian Standards. The conformity may be established through testing in a BIS recognized/ empaneled laboratory or testing in manufacturer's laboratory or a combination of both.
6. Water being used as an ingredient shall comply with IS 10500 (Drinking Water- Specification). Independent test report of drinking water as per IS 10500 shall be submitted with the application. The report shall not be older than six months. Water test report shall be verified during surveillance and re-certification audits also.
7. Process water being used for general operations such as washing, flushing, boiler feed, indirect cooling, etc shall comply with IS 4251 (Quality tolerances for water for processed food industry)

4.1 Demonstrating conformity of Product(s) to relevant Indian Standard(s):

The manufacturer may submit Independent Test Report from a Third Party laboratory recognized by BIS against the requirements as per relevant Indian Standards. Definition of Third party laboratory given in the Scheme- IX of BIS (Conformity Assessment) Regulations. A number of milk and milk products requires cold chain for transportation to laboratory for maintaining its integrity, therefore when a third party laboratory of BIS does not exist near the manufacturing facility and milk product is perishable i.e. having a shelf-life less than 10 days, the test reports from NABL accredited laboratories recognized by FSSAI may be accepted.

In any case, the independent test reports shall not be older than 90 days.

- A. In case of partial test report, remaining tests shall be either witnessed during the audit in the factory or in case test facility in the factory does not exist, sample shall be drawn for the rest.

Demonstration of Product Conformity	Grant of Licence
Independent Test report from Third party laboratory submitted with application	GoL on the basis of Test Report
Independent test report from third-party laboratory not submitted with application or Partial test report submitted	1) Complete factory testing 2) Partial factory testing 3) If 1) or 2) not possible sample may be drawn for complete test/ remaining test as applicable GoL based on factory Test Report/ Receiving of Independent test report as applicable

4.2 Conformity of Process Requirements

Process requirements are given in [Annexure II](#) of the scheme document. The assessment of process requirements is done during Stage 1 and Stage 2 audit through the Checklist for [Stage 1](#) and [Stage 2](#) audits.

Level of compliance during Stage 2 audit shall be as follows:

Sr. No.	Parameters	% Compliance
1.	Critical	100 %
2.	Major	Minimum 85 %
3.	Minor	Minimum 70 %

If percentage compliance is less than above criteria, non-conformity will be raised. The manufacturer has to take corrective action and inform. The verification of corrective action may be done through document review or through a follow up audit, as the case may be. Grant of Licence shall be only after fulfilling of above compliance criteria.

4.3 Conformity of FSMS Requirements

Food Safety Management system implemented by the organization shall be assessed during Stage 1 and Stage 2 audit.

In case, major non-conformities or a number of minor non-conformities are observed in the Food Safety Management System, a follow up audit may be called for.

5 Audit

The man-days required for Stage 1 and Stage 2 audit may be assessed in accordance with the [Guidelines for Audit time calculation](#). The competence of audit team members shall be as per the [Guidelines for Competence criteria](#).

The activities to be audited during Stage 1 and Stage 2 audit shall be as per Clauses of sub paragraph (2) of paragraph (3) of Scheme-IX of BIS (Conformity Assessment) Regulation, (Sixth Amendment) Regulations, 2021.

The audit team shall include at least one member from National Dairy Development Board (NDDB).

5.1 Stage 1 audit

Stage 1 audit under this scheme may be carried out for at least 2 mandays.

Stage I audit shall include verification of:

1. Availability of manufacturing machinery,
2. Availability of inspection and testing plan for each product,
3. Availability of test facility whether in-house or testing arrangement with BIS recognized laboratories,
4. Verification of hygienic conditions,
5. Competence of the Quality Control and Process Control Personnel; and
6. Evidence of product conformity to relevant Indian Standards as established through in-house testing records or through test reports from BIS recognized / empaneled Laboratory.
7. Readiness of the organization in terms of implementation of process requirements and FSMS requirements.

The outcome of Stage 1 audit determines whether the dairy unit is ready for Stage 2 audit.

Selection criteria for Stage 2 audit

The application will be processed for Stage 2 audit in case it conforms to the following requirements:

Sr No.	Assessment Score	Whether cleared Stage 1 and recommended for Stage 2 audit
1	Unit scores min. 70 % marks in Checklist for Stage 1 audit; and Milk and milk products conform to relevant Indian Standards; and No non-conformities raised in FSMS	Yes
2	Unit scores 60 to 70 % marks in Checklist for Stage 1 audit; and Milk and milk products conform to relevant Indian Standards; and Major/ Minor non-conformities raised in FSMS	Yes, subject to unit giving assurance for improvement up to 70% marks by the time inspection takes place.

3	Unit scores less than 60 % marks in Process requirements for Stage 1 audit; and/or Product not conforming to the relevant Indian Standards.	No
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Note-1: In case of units handling less than one lakh litres of milk per day (and having small milk procurement area) and which do not have BMC or chilling centre, the marks for Clause nos. 1.1 shall not be considered for calculation of percentage of marks.

The auditor is required to submit report for Stage 1 audit in the proforma, MSC-F9-01 ([Annex-IV](#)). The outcome of Stage 1 audit is calculated as percentage compliance in the [checklist for Stage 1 audit](#).

5.2 Stage 2 audit

The audit team shall submit Stage 2 audit report in the proforma, MSC-F9-02 ([Annex-V](#)).

Stage 2 audit shall include following assessment, but not limited to:

1. Compliance to the inspection and testing plan either through in-house testing records or results from BIS recognized/ empaneled Laboratory, wherever acceptable;
2. Level of compliance to process requirements using [Checklist for Stage-2 audit](#)
3. Visit to collection centers/ chilling centers;
4. Factory testing of milk and milk products, as applicable;
5. Verification of records;
6. Internal auditing and management review;
7. Performance monitoring, measuring;
8. Performance objectives and targets;
9. Ability to meet statutory/regulatory and contractual requirement;
10. Any other requirement as prescribed by the Bureau.

6 Grant of Licence

Based on satisfactory demonstration of compliance to the requirements, decision for Grant of Licence shall be taken by the DDGR. Licence may be granted for the scope as recommended by the audit team in [licence document](#).

7 Scope of Licence

The scope of licence shall include:

- i) Name of product(s) conforming to relevant Indian Standards,
- ii) Type(s), Grade, Variety
- iii) Material of packaging and pack size,
- iv) Conformity of Food Safety Management System implemented by the dairy unit/ organization to the requirements of IS/ISO 22000,
- v) Conformity of process requirements as prescribed in this scheme,

8 Validity of Licence

Validity of licence shall be 3 years from the date of grant of licence/ re-certification.

9 Fee

9.1 Marking Fee: The [fee prescribed under this scheme](#) is a consolidated fee structure for Product, Process and Management Systems Certification. The marking fee is calculated on the basis of volume of Liquid milk sold in case of liquid milk and Raw milk consumed in case of milk based products.

For existing product certification licensees, marking fee paid in advance to BIS shall be adjusted towards marking fee under this scheme from the time of grant of licence under this scheme.

9.2 Testing fee: The testing fee of samples shall be borne by the manufacturer.

10 Relaxations: Please see [Annex -A](#).



Annexure- A

Relaxations in auditing requirements for applicants having independent Product, Process or FSMS certifications

A.1 For applicants having product certification licence under Scheme I of BIS (CA) Regulations:

1. For Applicants whose products already certified by BIS to use ISI mark under Scheme I, the licences may be merged into this conformity assessment based on the performance of the licensee, results and date of last sample drawn.
2. If the organization is manufacturing products other than those already certified by BIS and is desirous of obtaining licence for the other products, demonstration of conformity shall be as per Clause 4.1.

A.2 For applicants having Quality mark from NDDB: A satisfactory report/certificate from NDDB may be obtained when Quality mark is valid at the time of applying to BIS under this scheme. NDDB's last assessment at factory shall not be more than 1 year old. In such cases, verification of process requirements is limited to Stage-1 audit only. The checklist for process requirements need not be verified during Stage 2 audit. The audit mandays may be accordingly adjusted, if required.

A.3 For applicants having accredited FSMS certificate either from BIS or other Certification body (CB): The licence may be granted under this scheme on the basis of verification of evidence of compliance to FSMS during initial certification.

A.3.1 FSMS licence from BIS: In case a dairy unit/ organization applying for certification under this scheme is holding a valid accredited Food Safety Management System certification as per IS/ISO 22000, the certificate may be accepted as demonstration of compliance.

A.3.2 FSMS certification from other Certification body (CB): FSMS certificate from IAF accredited CB may be accepted as evidence of conformity to the requirements of IS/ISO 22000. In addition to FSMS certificate, following documents shall be submitted by the applicant:

1. Satisfactory audit report issued by CB not older than one year
2. Undertaking to transfer the certification from other CB to BIS CAS before the end of its validity
3. Scope of FSMS certificate covering all products applied under this scheme.

Note-1: In case licence is granted on the basis of existing FSMS certification, Stage 2 audit may not include audit of FSMS. However, a re-certification audit/ Stage 2 audit shall be carried out before the end of validity of existing FSMS certification. The audit charges for this audit shall be collected from the licensee for calculated mandays.

Note-2: In case the scope of existing FSMS certification does not include all products for which the application has been submitted, auditing of FSMS for additional scope shall be carried out.

A.4 For applicants having FSSC certificate: After numerous deliberations with DADH, NDDB and Dairy organizations, it has been observed that various dairies are having FSSC 22000 instead of FSMS as per IS/ISO 22000. After a comparative analysis of FSMS vis-à-vis FSSC, it is understood that FSSC is a certification scheme based on FSMS and covers all requirements of FSMS. In addition, FSSC, lays down additional sector specific requirements.

laboratories								
5.Verification of hygienic conditions,	√	√	√	√	√	√	√	√
6.Competence of the Quality Control Personnel	√	√	√	√	√	√	√	√
7.Evidence of product conformity to relevant Indian Standards	√	√	√	√	√	√	√	√
8.Readiness of FSMS	√	√	Evidence for FSMS compliance	√	Evidence for FSMS compliance	Evidence for FSMS compliance	√	Evidence for FSMS compliance
9.Readiness for Process requirements	√	√	√	Evidence of conformity to Q mark guidelines	√	Evidence of conformity to Q mark guidelines	Evidence of conformity to Q mark guidelines	Evidence of conformity to Q mark guidelines
10. Additional Requirements for Stage 1 audit, if applicable	NA	Compliance to ITP and drawl of sample, if required	NA	NA	Compliance to ITP and drawl of sample, if required	NA	Compliance to ITP and drawl of sample, if required	Compliance to ITP and drawl of sample, if required

Stage 2 audit includes verification of:

1.Conformity of product based on independent test report or witnessing testing in factory	√		√	√		√		
2.Plant layout	√		√	√		√		
3.Manufacturing process	√		√	√		√		
4.Manufacturing machinery	√		√	√		√		
5.Test equipment and its calibration	√		√	√		√		

6.Competence of laboratory	√		√	√		√		
7.Personnel Hygienic conditions	√		√	√		√		
8.Compliance to Inspection and testing plan	√		√	√		√		
9.Storage facilities	√		√	√		√		
10. Drawl of sample, if required	√		√	√		√		
11. Audit of FSMS	√	√		√			√	
12. Compliance of process requirements	√	√	√		√			

Note- In case of organization having FSSC certification instead of FSMS, please refer A.6 above for requirements to be audited..

मानक: पथप्रदर्शकः

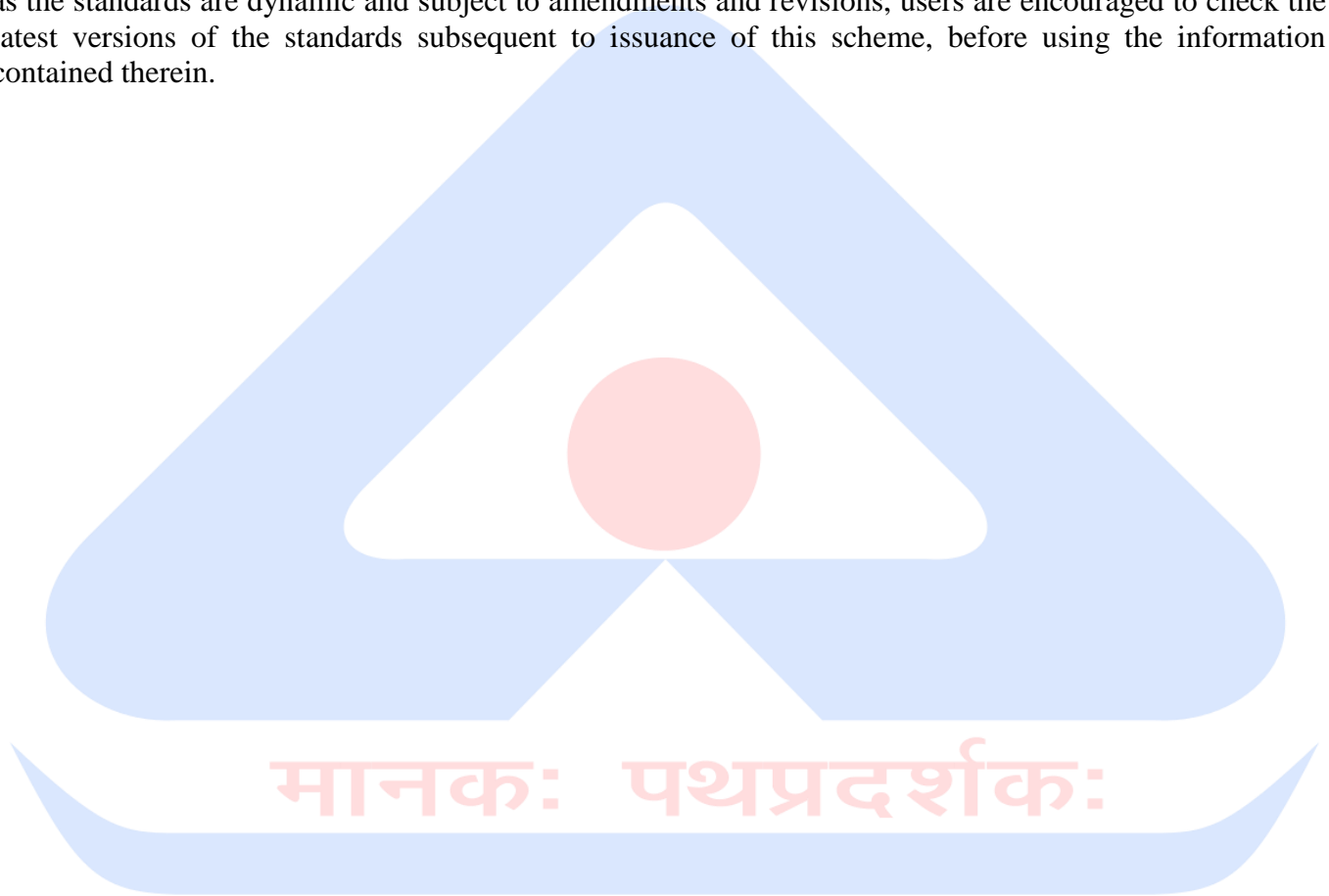
ANNEX-1
List of Indian Standards on Milk and Milk Products

Sl. No.	IS NO	TITLE	Product Manuals
1	IS 1000: 2021	Edible Lactose Specification (<i>second revision</i>)	https://www.bis.gov.in/wp-content/uploads/2019/05/PM-IS-10001.pdf
2	IS 1165: 2002	Milk Powder Specification (<i>fifth revision</i>)	https://www.bis.gov.in/wp-content/uploads/2020/09/PM-IS-1165.pdf
3	IS 1166: 1986	Specification for Condensed Milk, Partly Skimmed and Skimmed Condensed Milk (<i>second revision</i>)	https://www.bis.gov.in/wp-content/uploads/2019/11/PM_IS_1166.pdf
4	IS 1167: 1965	Edible Casein Products Specification (<i>second revision</i>)	Product Manual to be prepared after receipt of application
5	IS 1656: 2007	Milk-Cereal Based Complementary foods Specification (<i>fourth revision</i>)	https://www.bis.gov.in/wp-content/uploads/2020/05/PM-1656-CMD-2.pdf
6	IS 1806: 2018	Malted Milk Foods Specification (<i>second revision</i>)	https://www.bis.gov.in/wp-content/uploads/2020/05/PM-1806-1.pdf
7	IS 2785: 1979	Specification for Natural Cheese (Hard Variety), Processed Cheese, Processed Cheese Spread and Soft Cheese (<i>first revision</i>)	https://www.bis.gov.in/wp-content/uploads/2020/06/PM-IS-2785.pdf
8	IS 2802: 1964	Specification for Ice-cream	https://www.bis.gov.in/wp-content/uploads/2019/05/ICE-CREAM.pdf
9	IS 4079: 1967	Specification for Canned <i>Rasogolla</i>	Product Manual to be prepared after receipt of application
10	IS 4238: 2020	Sterilized and Ultra High temperature Sterilized Milk Specification (<i>first revision</i>)	Product Manual to be prepared after receipt of application
11	IS 4709: 2021	Flavoured Milk Specification (<i>first revision</i>)	Product Manual to be prepared after receipt of application
12	IS 4883: 1980	Specification for <i>Khoa</i> (<i>first revision</i>)	Product Manual to be prepared after receipt of application
13	IS 4884: 2021	Sterilized/ UHT Sterilized Cream Specification (<i>first revision</i>)	Product Manual to be prepared after receipt of application
14	IS 5162: 2021	<i>Chhana</i> Specification (<i>second revision</i>)	Product Manual to be prepared after receipt of application
15	IS 5550: 1970	Specification for <i>Burfi</i>	Product Manual to be prepared after receipt of application

16	IS 7839: 1975	Specification for Dried Ice-cream Mix	Product Manual to be prepared after receipt of application
17	IS 9532: 1980	Specification for <i>Chakka</i> and <i>Shrikhand</i>	https://www.bis.gov.in/wp-content/uploads/2020/06/PM-IS-9532.pdf
18	IS 9584: 1980	Specification for Cheese Powder	Product Manual to be prepared after receipt of application
19	IS 9617: 1980	Specification for Dahi	Product Manual to be prepared after receipt of application
20	IS 10484 : 2021	Paneer Specification (first revision)	Product Manual to be prepared after receipt of application
21	IS 10501 : 1983	Specification for Kulfi	https://www.bis.gov.in/wp-content/uploads/2020/04/PM-IS-11501-1-April-2020.pdf
22	IS 11602 : 1986	Specification for Packed Gulab Jamuns	Product Manual to be prepared after receipt of application
23	IS 12176 : 1987	Specification for Sweetened Ultra High Temperature (UHT) Treated Condensed Milk	Product Manual to be prepared after receipt of application
24	IS 12299 : 2021	Dairy Whitener Specification (second revision)	https://www.bis.gov.in/wp-content/uploads/2021/07/PM_IS_12299_July_2021.pdf
25	IS 12898 : 1989	Dairy Products Yoghurt Specification	Product Manual to be prepared after receipt of application
26	IS 13334 : Part 1 : 2014	Skimmed Milk Powder Specification Part 1 Standard Grade (second revision)	https://www.bis.gov.in/wp-content/uploads/2020/09/PM-for-IS-13334-Part-1.pdf
27	IS 13334 : Part 2 : 2014	Skimmed Milk Powder Specification Part 2 Extra Grade (first revision)	https://www.bis.gov.in/wp-content/uploads/2020/05/PM-13334-Pt-2.pdf
28	IS 13688 : 2020	Packaged Pasteurized Milk Specification (second revision)	https://www.bis.gov.in/wp-content/uploads/2020/12/PM_IS_13688_01012021.pdf
29	IS 13689 : 2021	Butter Oil and Anhydrous Butter Oil Specification (first revision)	Product Manual to be prepared after receipt of application
30	IS 13690 : 2021	Butter Specification (first revision)	Product Manual to be prepared after receipt of application
31	IS 14433 : 2007	Infant Milk Substitutes Specification (first revision)	https://www.bis.gov.in/wp-content/uploads/2020/06/Revised-PM-for-IS-14433.pdf
32	IS 14542 : 1998	Partly Skimmed Milk	https://www.bis.gov.in/wp-content/uploads/2019/06/Product-Manual-IS-

		Powder Specification	14542.pdf
33	IS 15757 : 2007	Follow-up Formula - Complementary Foods Specification	https://www.bis.gov.in/wp-content/uploads/2020/06/Revised-PM-IS-15757.pdf
34	IS 16326 : 2015	Ghee Specification	Product Manual to be prepared after receipt of application

Note- All efforts have been made to incorporate details as per the latest version of the standard. However, as the standards are dynamic and subject to amendments and revisions, users are encouraged to check the latest versions of the standards subsequent to issuance of this scheme, before using the information contained therein.



ANNEX- II

PROCESS REQUIREMENTS

A. Milk production, and collection /handling of raw milk

1. Primary Production Holding

The quality and food safety aspects of raw milk are influenced by a number of factors such as – nutrition, management, health status of milch animal, environment etc. Therefore, it is necessary that proper care is taken at the primary production holding for Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP) and the guidelines and procedures prescribed by the Codex as per “Code of Hygienic Practice for Milk and Milk Products” are effectively followed.

The processing unit should be in a position to exercise effective control on the primary production holding to ensure that the quality and food safety aspects of the raw milk are taken care. The unit should arrange for providing training to milk producers to follow recommended practices for milch animal upkeep and adopting hygienic practices and records of such trainings shall be maintained properly.

In addition, the unit should undertake periodic audit of primary production holdings to ensure that the recommended hygienic practices are followed.

2. Collection and transportation of raw milk to processing unit

As Raw Milk is highly perishable in nature; care should be taken during milk collection, storage and transportation to the processing unit so that the quality and food safety of milk are not compromised.

i. At village collection level

The care to be taken at the village level collection centre to include:

- a. Proper location, building quality so as to prevent contamination from chemicals, insect/pest, biological and other hazardous substances.
- b. Use of proper milk collection equipment – preferably from SS (as per AISI 304 grade).
- c. Proper cleaning and sanitation of milk storage vessels (cans).
- d. The practical (as far as possible) arrangements for cooling the milk including use of suitable technologies (BMCs).
- e. Proper personal hygiene and cleaning /sanitation protocol at the centre.

ii. Transportation of milk to milk processing unit

The transportation of raw milk to processing unit shall be done in clean vehicle/insulated milk tanker to avoid any chemical/biological contamination of the raw milk. Adequate precautions also need to be taken to ensure that integrity of milk is maintained.

B. Processing unit

3. Location and Surroundings

- i) The establishment shall be so located that neighboring buildings or operation and land use present no source of potential contamination for the hygienic operation of the facility. The establishment shall be located in an area away from objectionable odours, smoke, dust, other contaminants including flooding; or near-by slaughter houses.
- ii) The surrounding shall be reasonably free from objectionable odours, smokes, dust and other contaminants. The establishment shall be reasonably away from sewage treatment plants, sewage pump stations, cemeteries, cement factories and or other chemical factories.
- iii) The premises shall be kept clean and roads in the premises shall be concreted / tarred or turfed to prevent windblown dust, formation of soil and water mix.
- iv) There shall not be any stagnant water or signs of any rodent harbourage inside the premises.

4. Constructions and Layout of building of Plant

- i) The establishment shall be housed in a building of permanent nature affording sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions.
- ii) The design and layout shall be such as to preclude contamination.
- iii) The layout of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination and backtracking. All the milk products handling areas shall be separate from areas used for residential purpose.
- iv) There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering.
- v) The layout shall ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion.
- vi) The building shall provide sufficient protection against the entry and harbourage of rodent, insects, milch animals, other animals etc.
- vii) All the entry points shall have suitable air curtains or other suitable arrangements to prevent the entry of flies.
- viii) Non-operative areas inside the establishment shall be properly cordoned

off to avoid possible cross- contamination.

5. Hard Park for receipt of vehicles for milk delivery by cans/other vehicles

The hard park area should not be 'kachha' but properly cemented and should have proper slope and arrangements for drainage which does not cause contamination of raw milk, finished products etc.

6. Milk receiving section

- i) There shall be a raised platform for receiving the material and the sides and roof of the platform shall be so constructed to provide protection from extraneous contamination.
- ii) The outside of the platform should be provided with sufficient protection to avoid vehicles hitting the platform and damaging.
- iii) The raw milk receiving section shall be sufficiently separated from processing area to prevent contamination.
- iv) Signboards directing the employees to wash and sanitise hands before entering and after each absence shall be installed.
- v) Air curtains/fly killers shall be installed to prevent the entry of flies when the door is opened.

7. Tanker cleaning infrastructure

The unit should have proper infrastructure for:

- a. There shall be proper arrangement for tanker cleaning. Tanker bay with CIP facility is required.
- b. Cleaning and sanitation of the tanker including milk contact surface of barrel, hose pipe, pump etc. after unloading of milk.

8. Floors, walls and Ceiling

- i) The floor of the processing areas shall be smooth, impermeable and easy to clean and disinfect. There shall be no water stagnation on the floor. The floor shall have sufficient slope opposite to the flow of work or sideways.
- ii) The wall to floor and wall-to-wall junctions shall be rounded off to facilitate easy cleaning.
- iii) The walls should be durable, smooth, light coloured and easy to clean and disinfect. The walls should preferably have glazed tiles/ other tiles up to a height of minimum six feet.
- iv) The walls should not have projections and the entire fitting on the wall shall be made in such a way so as to clean and disinfect them easily. If possible, the electric switches or other fittings shall be fixed in areas where no handling of

milk product is carried out.

- v) The walls and pillars should be suitably protected (by SS ring/cladding) to prevent damage by equipment hitting these.
- vi) The ceiling shall be free from cracks and open joints and shall be smooth and easy to clean.
- vii) If structural elements or fittings are suspended below the ceiling, suitable protection shall be given to prevent falling of debris, dust or bird dropping.

9. Doors, Windows, Ventilators, Stairs, Platforms and Stands

- i) All the doors shall be tight fitting and the windows and ventilators shall have fly proofing nets to prevent the entry of flies.
- ii) All doors and windows shall be durable and made of corrosion resistant material and windowsills, if any, shall slope inwards. The windows/ ventilators shall be constructed at least one meter above the floor.
- iii) The doors shall be of self-closing type.
- iv) Open windows are not permitted in areas where food is exposed, processed or packed.
- v) Mechanical ventilation/ exhaust fans shall be provided in areas where stagnation of air, condensation of fluid etc. are present.
- vi) The opening of ventilation/ exhaust fan shall be provided with suitable fly proofing system.
- vii) Stairs, catwalks, platforms, stands, ladders and the like in processing areas shall be of a construction and material that is impervious, non-corroding, easy to clean and impact resistant. These should be situated and constructed so as not to cause contamination of food processing areas, equipment and product by allowing potential contaminants falling onto them.

10. Drainage

- i) There shall be adequate drainage facility and slope of the drainage shall be opposite to the flow of work/material.
- ii) The open end of the drainage shall be protected against the entry of rodents.
- iii) The drains shall be of adequate size having sufficient slope for easy cleaning.
- iv) All drains shall:
 - be provided with Amul type trap
 - have adequate access for cleaning
 - Where necessary, be adequately vented to the exterior of the building.
- v) Floor drains shall not be connected to drains from toilets.
- vi) Floor drains should not be connected to the storm or rain water drainage system. Where this occurs, they shall be designed and maintained in a manner to

ensure that flooding of the premises cannot occur due to back-flow.

vii) Tables, Utensils, Equipment's & Machineries

- a. All the utensils and equipment shall be made of non-corrosive material (SS as per ISI 304) and shall be smooth without cracks and crevices and easy to clean and disinfect.
- b. All food contact surfaces shall be free from rust and paints.
- c. Suitable arrangements shall be made to drain the water from the tables directly into the drainage without falling on the floor.
- d. Freezing equipment shall be suitable to freeze milk products and shall achieve the required core temperature within the stipulated time. The equipment shall be fitted with necessary gauges to indicate the temperature, pressure etc. The recording devices shall be calibrated at specified intervals.
- e. Pasteurizers of suitable capacity having capability to maintain required temperatures and time shall be provided with automatic calibrated temperature devices.
- f. Milk products store rooms shall be clean having smooth floor, walls and roof and shall have suitable mechanism to control the temperature, if required.
- g. Spray drying facility shall be equipped with approved air filters.

viii) Chill Rooms, Cold Storages, Tunnel and Deep freezers

- a. Chill rooms/storage tanks/silos having adequate size with mechanical refrigeration system to maintain temperature at the required level (0°C to 4°C) shall be provided in the processing section or outside.
- b. The cold storage/tunnel and Deep freezers shall have suitable refrigeration system to maintain the required product
- c. temperature.
- d. The floor, ceiling and walls of the cold storage and other storage rooms shall be smooth and easy to clean and disinfect.
- e. Proper steps shall be taken to avoid contamination of the materials stored.
- f. There shall be adequate lighting with protective covers.

ix) Change Rooms and Toilets

- a. Adequate number of change rooms for workers shall be provided for high risk and low risk areas.
- b. The change rooms shall be of adequate size having smooth washable walls and floors.
- c. There shall be flush lavatory and the lavatories shall not open directly to the working area.
- d. The change rooms shall have foot-operated washbasins provided with adequate

soap and single use towels. There shall be a foot operated waste bin to collect the used towels.

- e. There shall be lockable cupboards and facility for keeping gumboots, shoes and chapels inside the change room.
- f. Suitable arrangements shall be made by the establishment to launder the working clothes of the workers.
- g. The toilets shall have self-closing doors and proper fly proofing system.
- h. Toilets and toilet area should be adjacent but separate from change room and at the same time shall be integrated with the processing facility but completely separated from handling areas and not open directly onto these areas. These should be

- 1. designed to ensure hygiene removal of waste matter
- 2. well lit, ventilated and maintained clean at all times.

- a. The number of toilet bowls to be provided is as follow: No. of persons

	<u>No. of bowls</u>
1 to 9	1
10 to 24	2
25 to 49	3
50 to 100	5
For each additional 30 persons excess of 100 persons)	1 (additional bowl) (in

- a. In male toilets, urinals can substitute for toilet bowls for up to 1/3rd of the total toilets required.
- b. Entrance to toilets from processing areas shall be either through an intervening change room or an airlock that is vented to external air.
- c. Doors for toilet cubicles where they are not in a separate toilet room must be self-closing and tight fitting.

x) Workers entry points

- a. Suitable washing and sanitizing facilities for feet and hands shall be provided at the entry points.
- b. The washbasins shall be provided with foot operable taps or non-hand operable taps.
- c. Liquid soaps, disinfectants, single use towels / hand dryers etc. shall be provided in sufficient quantities at all entry points.
- d. Waste bins provided for collecting used towels shall be of foot- operated type.

xi) Store rooms

- a. There shall be separate stores for wet and dry items and the chemicals/ disinfectants should be properly labelled.
- b. Packing material store shall be of adequate size with proper fly and dust proofing system.
- c. Cartons shall be kept on cleanable pallets other than wood, away from the walls and covered properly. There shall be enough space for a person to walk around.
- d. Pest and rodent control measures shall also extend to the storerooms.

xii) Water

- a. Water used in the factory shall be of potable nature and shall meet statutory requirements as applicable (IS: 4251 and/or IS: 10500).
- b. Potable water shall be used also for cleaning utensils, machinery, tables etc.
- c. A suitable water management system shall be followed and this shall include use of plumbing diagrams showing the entire reticulation of the water, identifying each tap with consecutive numbers.
- d. Water store tank, both ground level and overhead, should be well protected and cleaned regularly.
- e. The taps having hose connections shall be fitted with non- return valves.
- f. The water tanks shall be cleaned regularly as per SOP as per pre-decided frequency.
- g. If water is brought from external source i.e. mobile water tankers, it should be cleaned and disinfected periodically.

xiii) In-house laboratory

- a. The establishment shall have a well-equipped in-house laboratory for testing microbiological and other chemical parameters.
- b. The testing shall be done by qualified and trained lab persons/veterinarian/ technologist (s) (Refer Annexure- 3 for Assessment of Manpower).

xiv) Transportation facilities

- a. The establishment shall have suitable and adequate facilities for the transportation of raw material, finished products etc.
- b. The food contact surfaces of the vehicles shall be made of non-corrosive material (Stainless Steel - as per AISI 304); it shall be smooth, and easy to clean and disinfect.
- c. Vehicles shall be maintained properly and records maintained thereof.

xv) Retail outlets

The area around self-owned/operated retail outlets shall be clean and free from filth, dust etc. (as per Section 1 above)

xvi) General Maintenance of Facilities

- a. Buildings vessels, equipment, utensils, refrigeration and all other facilities of a processing including drains shall be kept in good repair in a clean and orderly condition.
- b. Repairs shall be carried out as soon as possible without interference to handling and processing.
- c. In case of major repairs and or maintenance, which may affect the safety or contaminate the product, production shall be stopped so as carry out the repairs and or maintenance.
- d. There shall be a documented procedure for maintenance of all sections, equipment, machineries etc.
- e. The machineries/ equipment's shall be marked with suitable identification numbers.
- f. The building should be whitewashed regularly as per the schedule.

xvii) Cleaning and Sanitizing

- a. All chemical compounds used as cleaners, sanitizers, soaps, detergents, shall be of standard make.
- b. Cleaning should be carried out immediately after the end of work for the day or at such times as may be appropriate/ documented to maintain hygienic conditions, floors including drains and additional structures, processing equipments and wall of food handling areas must be thoroughly cleaned.
- c. To prevent the contamination of food equipments, utensils and food contact surfaces shall be cleaned as frequently as necessary as per the documented procedures.
- d. These should be sanitized when there is a risk of contamination but not less than daily.
- e. Food contact surface must be adequately rinsed after the use of any detergents prior to handling of the food.
- f. Adequate precautions shall be taken to prevent food from being contaminated during cleaning or sanitizing of rooms, equipment or utensils.
- g. Detergents and sanitizers shall be suitable for use in food handling areas and not impart any flavours, odours or leave toxic residues.

- h. Detergent and sanitizers shall be diluted for use according to the manufacturer's instructions.
- i. Cleaning personnel shall be trained in handling and use of cleaning without cross-contaminating the products and or food contact surfaces.
- j. Staff change room, shower room, toilets and cafeteria, shall be kept clean at all times.

xviii) Hygiene Control Program

- a. A documented predetermined cleaning and sanitation program shall be in place at each facility.
- b. All cleaning personnel shall be suitably trained in cleaning and sanitizing techniques.
- c. All cleaning operations shall be carried out under the adequate supervision of designated personnel.
- d. All cleaning and sanitation procedures shall be monitored, verified and records maintained.
- e. Monitoring effectiveness: Cleaning and Sanitation system should be monitored daily/as per schedule for effectiveness, periodically verified by means such as audit, preparation inspections or where appropriate microbiological testing of environment and food contact surfaces and regularly reviewed and adapted to reflect change circumstances

xix) Personal Hygiene

- a. Unhygienic behaviour that can result in the contamination of food products such as chewing, eating, spitting, scratching of body parts with hands, putting fingers in nostrils, ears etc. shall be avoided inside the facility, specifically in processing/product manufacturing and handling area.
- b. A person shall be made responsible for maintenance of personal hygiene and health status of the workers.
- c. The employees engaged in processing activities shall be free from communicable diseases, open sores and wounds.
- d. They shall be medically examined periodically and unit shall maintain individual health cards issued by an approved medical officer showing that they are fit to handle food products and suitable to work in milk processing plant.
- e. Smoking should be strictly prohibited in the entire premises including office area.
- f. All personnel shall wash and sanitize their hands:
 - 1. prior to entering the processing areas
 - 2. immediately after using toilet
 - 3. after handling dirty or contaminated materials

4. after undertaking cleaning procedures – involving handling of sanitizers and similar cleaning chemicals
 5. after handling food, ingredients and items used in food handling immediately after handling any material that may be capable of transmitting contaminants.
- g. Prophylactic injections shall be administered to the employees and record maintained thereof.
 - h. Communicable diseases in their homes shall also to be notified and the employee shall be medically examined after each absence due to illness.
 - i. All workers shall be provided with sufficient sets of clean work dress and headgears.

xx) Inedible By-products and Materials

- a. Inedible by products shall:
 - i. be stored so as to avoid contaminating food for human consumption
 - ii. be removed from the food preparation area as often as necessary to avoid cross contamination
- b. All equipment used for the disposal, storage and treatment of wastes or inedible material shall be clearly identified, stored separately and not used for edible material.
- c. Cleaning and sanitizing of utilities and equipment for in- edible materials shall be carried out in a physically separate area.

xxi) Storage and Disposal of Waste

- a. Provision shall be made for the storage of waste and inedible material prior to the removal of waste from the factory.
- b. Waste storage facilities shall be:
 - i. away from the processing area
 - ii. designed to prevent access to waste by pests
 - iii. designed to avoid contamination of food, potable water and equipment's.
- c. Waste shall be removed from food handling areas and other facilities either at the end of the shift or when the containers are full.
- d. Immediately after the disposal of waste, receptacles used for the storage and any equipment which has come into contact with the waste shall be cleaned and sanitized.

The waste storage area shall be kept clean.

- e. All waste disposal bins shall be foot operated with tight-fitting lids.
- f. The storage and handling of waste shall be as per Pollution Control Board (PCB) norms.

xxii) Pest Control

- a. There shall be a documented pest control and monitoring programme concentrating more on the prevention rather than eradication.
- b. There shall be an effective and continuous schedule for the prevention, detection control and eradication of pests.
- c. Pest control shall not constitute a hazard to human health and product safety.
- d. Control measures involving treatment with chemicals shall only be undertaken by trained and competent personnel. Trained and competent personnel should have complete understanding of the health hazards these chemicals may pose to the product and human.
- e. Accurate and legible records of the location and frequency of pest control measures shall be kept and made available to the Team for verification.
- f. A bait map shall be kept and made available on request for verification.
- g. Where pest control is entrusted with an outside professional agency or contractor, the effectiveness of the pest control program shall be monitored by responsible personnel in the facility and records shall be maintained for corrective action
- h. Preventive action in case of failures. The details of the inventory of the past control chemicals used by the pest control personnel shall be available for verification of their suitability and minimized and the hazard due to pest chemicals are under control.

xxiii) Storage of Hazardous Substances

- a. Pesticides, cleaning agents or other substances which could represent a hazard to health and food shall be suitably labelled with a warning about their toxicity and use and care be taken to avoid the chemicals contaminating food, food contact surfaces and ingredients.
- b. Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorized and properly trained persons.
- c. Wet and dry chemicals shall be stored separately to avoid accidental mixing due to leakage or spillage.

- d. No substances which could contaminate food may be used or stored in food handling areas or be stored with any product, ingredients or product packaging materials.
- e. The detergent/disinfectant in use inside the processing facility shall be located at a designated place and labelled legibly. The same shall not be stored in any food containers.

Note – Also see

IS 7005 Code for hygienic conditions for Production, Processing, Transportation and Distribution of milk.

IS 2491 Food Hygiene- General Principles- Code of Practice

This is for information only



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ANNEX-III
FORM- 1
BUREAU OF INDIAN STANDARDS
APPLICATION FORM FOR LICENCE TO USE THE STANDARD MARK
 Integrated Product, Management system and process certification scheme

Full Name of Firm

Office	Address					
					Tel	
					Fax	
Village/City	District	State	Country	Pin Code	E-mail	

Factory	Address					
					Tel	
					Fax	
Village/City	District	State	Country	Pin Code	E-mail	

Top Management details	Name	Designation	Technical Management details	Name	Designation
	1			1	
	2			2	
	3			3	
	4			4	
Contact Person	Name		Tel	E-mail	

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Correspondence Address	Office	Scale of Unit	Large	Sector	Public
	Factory		MSME (Mention, whether Micro, Small or Medium)		Private

Number of shifts in a day	
Weekly off (if any)	

This application is made to obtain BIS licence for usage of Standard Mark on:

Sr. No.	Product	Indian Standard Specification	Varieties (Grade/Type/Class etc.)
(i)			
(ii)			
(iii)			
(iv)			

The associated management system(s) for compliance is/are as per Indian Standard(s)

The associated process compliance requirement(s) is/are

Indicate availability of following documents and submit along with the application form:

Sr. No.	Document(s)	Yes/No/Not applicable
(i)	a) Establishment of firm, such as Certificate of incorporation issued by the Registrar of Firms or Societies/Directorate General of Technical Development/ Director of Industries or similar other documents authenticated the name of firm and its premises) b) Address proof of the factory c) Valid Micro, Small and Medium Enterprises certificate, if applicable d) Authorized representative letter, in case application signed by person other than Chief Executive Officer of the firm	
(ii)	a) Inspection and testing plan for each product b) Manufacturing machinery list c) Testing equipment list with calibration status	

	d) Plan layout (indicative sketch, need not be to exact measurements/scale) e) Process flow chart with details of installed production capacity and estimated value f) Details of outsourced operations and controls exercised h) Raw materials used for each product, as applicable	
(iii)	a) Test report(s), in-house/third party laboratory b) Documentation on compliance to management system (For example; policy/procedures/manuals, as applicable) c) Compliance to process requirements, as specified d) Number of personnel involved in scope of certification	
(iv)	Declarations, as applicable	

Declarations:

- (i) I/We have necessary consents/clearances as per the provisions of Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981 respectively under the Environment (Protection) Act, 1986. (If applicable)
- (ii) I/We further undertake to modify, amend or alter my/our documented information to bring it in line with the requirements of the relevant standard and/or as required by Bureau of Indian Standards from time to time.
- (iii) I/We agree to pay fee prescribed by the Bureau as applicable and as given in the scheme and/or as per the agreement/quotation letter No. _____ dated _____
- (iv) I/We have read the conditions of licence and hereby undertake to abide by them as mentioned in the guidelines for applicants and the regulations framed under the Bureau of Indian Standards Act, 2016.
- (v) Should any initial enquiry be made by the Bureau, I/We agree to extend to the Bureau all reasonable facilities at my/our command and I/We also agree to pay all expenses of the said enquiry, as and when required by the Bureau.
- (vi) Certified that I/We had earlier applied for a licence to Bureau of Indian Standards for _____ on _____ which could not mature.
- (vii) I/We have not been convicted under the Bureau of Indian Standards Act in any court of law and neither any prosecution is pending.

OR

The details of convictions/prosecutions pending under the Bureau of Indian Standards Act are as under: _____

- (viii) I/We have never been warned/advised by Bureau of Indian Standards for any of our actions violative of the Bureau of Indian Standards Act/

OR

The details of warning/advice received by me/us for violating the Bureau of Indian Standards Act are _____ as _____ under: _____

- (ix) The information given in this application form are true to the best of my/our knowledge and belief. I/We shall be responsible, if any misleading information given in this form and the application shall be liable for rejection if any wrong information has been given. If the licence is

granted on the basis of information which is found to be incorrect later, the licence shall be liable for cancellation.

Explanation.- For the purpose of this form, the expression micro, small and medium enterprises shall have the meaning assigned to it in the Micro, Small Medium Enterprises Development Act, 2006 (27 of 2006), as amended from time to time.

The information obtained by the Bureau and its certification officers from any statement made or information supplied or any evidence given or from factory visit(s) shall be treated as confidential by the Bureau as per provision of sub-section (5) of section 27 of the Bureau of Indian Standards Act, 2016.

Note: For more details, you may please visit our website <https://www.bis.gov.in/>

Fee Details	Amount (₹)	Receipt/transaction details

Seal of Firm		Signature Name Designation Date of application	
PAN or Business licence no. of Firm		DIN no.(in case of director) PAN no. (for other cases)	

Important: Application should be signed by Chief Executive Officer of the firm, or in his absence by authorized representative

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ANNEX-IV
AUDIT REPORT FOR STAGE-I AUDIT CONFORMITY ASSESSMENT SCHEME FOR MILK & MILK PRODUCTS

Part A - General

1. Application/ Licence No. :
2. Name & Address of the organization :
3. Products/Indian Standards to be covered :

Product	IS	Variety

4. Confirmation of the information provided in the application:
5. Auditor's Name and Designation :
6. Date(s) of the Audit :

Part B – Review of Product Certification Requirement

1. Whether unit already having licence for Product Certification: : Yes/No
i) If yes,

Indian Standard	Product	Licence No.	Validity

ii) If No or if additional products are to be included in the scope of this licence, fill clause 2 to 11

2. Layout Plan of Factory* submitted with application : Yes/ No
3. Process Flow* submitted with application : Yes/ No
4. Availability of Manufacturing Machinery* declared in application : Yes/ No
5. Availability of test equipment* declared in application : Yes/ No
6. Availability Quality Control and Process Personnel : Yes/ No
7. Remarks on Competence of Quality Control and Process Personnel :
8. Review of inspection and testing plan for each product :
9. Verification of Product Conformity to relevant Indian Standard for each product : (See Table 1)
10. Identify and list products where complete factory testing is required (For products where complete Test Report (TR) is not available, complete/ partial factory testing may be done in the premises during Stage-2 audit) : (See Table 1)

Product	IS	Inspection and Testing Plan (Specify whether BIS ITP implemented or In-house Plan)	Whether complete TR available (In-house or Outside Laboratory)	TR Satisfactory/ Unsatisfactory	Time required for factory testing for complete or remaining tests

(Table 1)

11. Estimate time required for complete factory testing as identified at sl.no. 9 above:

*Note- Attach Documents only if different from the documents submitted with application

Part-C - Review of Process Requirements

1. Whether unit already certified for Process Requirement : Yes/No
If yes,
a) Enclose valid certificate and last assessment report:
b) Whether the last assessment report is satisfactory:
2. Remarks on Hygienic Conditions:
3. Any Non-conformities or Concerns:

Part-D - Review of FSMS Requirements

1. Whether unit already certified for FSMS : Yes/No
If yes,
a) Enclose valid certificate with scope of certification:
b) Is last assessment report is satisfactory:
c) Enclose undertaking for transfer of certification to BIS, if applicable:
2. Procedure & other related Documents : Attach list of documents and records maintained by the firm if not submitted or different from application (enclose report as Annexure-)
3. Identification of processes :
4. Identification of objectives :
5. Scope of the Food Safety Management System (FSMS) : Enclose *declaration from Applicant*
6. Time allocation of FSMS for second stage audit: enclose report as Annexure (*Use Guideline for Audit Time estimation. Consider time required for visit to milk chilling centers*)
7. Legal and statutory requirements : enclose report as Annexure (*Please attach declaration from applicant*)
8. Last Internal audit :
9. Any non-conformity raised during internal audit : Yes/No.

10. Corrective actions completed against non-conformities raised during internal audit: Yes/ No

8. Last Management Review undertaken on:

9. Any issues of concern :Yes/No. If Yes, enclose report as Annexure*

* Note: Attach sheet, if required

Part E - Recommendations

1. Percentage Compliance of Stage-1:

1. Status of implementation of CAS : Ready for Stage-2 Audit or Not
(Give reasons if not ready)

2. Total Time recommended for Stage -II audit including conformity to Management System, Product requirements and process [B11 + C5] : [] mandays.

3. Whether operations are carried out in shifts : Yes/No
If yes, whether audit is required in other shifts : Yes/No
If No, give reasons:

4. Conclusion and Recommendation:

Name and Signature of Auditor:
Date:

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**CHECKLIST FOR PROCESS REQUIREMENTS TO BE VERIFIED DURING
STAGE 1 AUDIT**

Name of Dairy Unit/ Organization:

Address:

Date of Visit:

Sl. No.	Requirements	Scoring criteria	Assessment Score
1	Raw Milk Procurement System		
1.1	Preliminary Assessment Criteria Assessment Grade /Marks * Parameter Actual Status/Value 1 Raw milk procurement system 1.1 Percentage of raw chilled milk coming from BMC set up either owned/controlled by the unit or by other organizations which follow the procurement system duly audited and certified by the unit.	Above 50% = 3 30-50% = 2 Less Than 30% = 1	
1.2	MBRT of incoming raw milk	more than 90 min = 3 60 – 90 min = 2 less than 60 min = 1	
2	Processing Infrastructure and its Management		
2.1	Does the unit have proper infrastructure / manufacturing machinery	Satisfactory-3 Needs Improvement-1	
2.2	Are there adequate number of qualified and trained personnel	As given below	
2.3	Verification of hygienic condition	Satisfactory-3 Needs Improvement-1	
3	Laboratory Infrastructure and its Management		
3.1	Does the unit have laboratory setup/ arrangement for testing milk and milk products as per relevant Indian Standards under the scope of this certification	Satisfactory-3 Needs Improvement-1	
3.2	Adequate number of trained and qualified manpower employed for the laboratory operation	As given below	
3.3	Whether liquid milk is being distributed/sold through insulated vehicles	Satisfactory-3 Needs Improvement-1	
3.4	Failure of products samples of the unit tested by food regulator in last one Year	Nil Failure- 3 1 or more failure- 0	

4	Conformity to relevant Indian Standards		
4.1	Availability of Inspection and testing plan for each product*	Satisfactory-3 Unsatisfactory-0	
4.2	Evidence of conformity of milk and milk products to relevant Indian Standards*	Satisfactory-3 Unsatisfactory-0	
5	Conformity to Food Safety Management Systems	Satisfactory-3 Needs Improvement-1	Attach Stage I audit report



Assessment of Manpower

The desirable qualification and experience of the manpower should be as under:

S. No.	Designation	Qualification	Marks
1	Plant manager and next in the line below (top two/three levels)	<p>A. Minimum B Sc/ B Tech. (Dairy Technology) with minimum 8 years' experience in dairy Plant/ IDD with 15 years of experience in dairy Plant.</p> <p>B. Minimum M Sc/ M Tech in Dairy Technology Dairy Chemistry Dairy Microbiology ; or M Tech / ME in Food Technology with at least five years of experience in Dairy Units.</p> <p>C. Minimum B Sc/ B Tech (Dairy Technology) with minimum 4 years' experience in dairy Plant.</p> <p>D. Other qualification such as B Sc / M Sc Science, Agriculture (with Dairy technology as one of subjects), with or without experience/ or otherwise experienced senior managers.</p>	<p>If A and B = 3</p> <p>If C and D = 2</p>
2	Laboratory In- charge and next level (two top levels). The Number of manpower shall depend upon level of automation etc. details to be provided.	<p>A. M. Sc/ M tech in Dairy /Food Technology, Dairy / Food Chemistry Dairy / Food Microbiology with minimum 3 years' experience in dairy sector.</p> <p>B. B Tech in Dairy / Food Technology or M Sc Microbiology / Chemistry / Biotechnology with minimum 5 years' experience in dairy sector/ IDD with 15 years of experience in dairy.</p> <p>C. B Sc (Microbiology /Biotech/Chemistry / Biology) and with 7 years experience in dairy sector and with proper training at a reputed organization in field of dairy lab training Tech in Dairy / food Technology</p>	<p>If A and B = 3</p> <p>If C = 2</p>

ANNEX-V

AUDIT REPORT FOR CONFORMITY ASSESSMENT SCHEME FOR MILK AND MILK PRODUCTS (INITIAL/ RE-CERTIFICATION)

Section 1 Organization Details

1.1 Application/Licence No.:	
1.2 Name of the Organization	
1.3 Complete Address	
1.4 Telephone & Email address.	
1.5 Name of the concerned Contact Person (with E-mail id)	
1.6 Telephone No.	
1.7 Effective no. of personnel	
1.8 No. of shifts	

Section 2 Audit Details

2.1 Audit Criteria [Management System Standard, relevant Indian Standard(s), organization's documented information (Title, Issue No., Date, No. of Amendments, etc.)]	
2.2 Objectives & Scope of Audit (organizational and functional units or processes to be audited. For multi- site audit mention the actual sites being audited)	
2.3 Date(s) of Last Audit	
2.4 Audit Dates	
2.5 Duration (mandays)	
2.6 Non applicability of process(es), where applicable, sought by the firm and verification of justification by the Audit Team.- Audit observation sheet also reflect the justifications and evidences related to the applicable processes	
2.7 Scope to be covered in the licence document (<i>Attach letter from the organization for the scope sought with details of products/Indian Standards to be covered, duly countersigned by Team</i>)	

<i>Leader. Ensure that the audit plan and observations cover the scope) :</i>	
Name & Signature of Team Leader	Date of report
<u>MSCO(R)</u>	
<u>DDG(R)</u> _____ - in case audit is undertaken by MSCO(R)	
<u>DDG(MSCD)/ADG</u> - Through MSCO(R) in case audit is undertaken by DDG(R)	

<u>Section-3 : Conformity of Product</u>
Packaging and Marking
Laboratory and Inspection
Availability of competent personnel
Whether “Equipment and other facilities for complete testing as per Indian Standard Specification Testing equipment/chemicals” different from application Submission
Whether “Accuracy of Instruments and arrangements for calibration” different from application Submission
Factory Testing (Template format for Factory test Report is enclosed at the end. Enclosed separate test report for each product)
Testing in factory
मानक: पथप्रदर्शक:
i) Name of Product
ii) Variety
iii) Batch Number/Lot Number
iv) Date of Manufacturing
v) Best Before/ Shelf Life
vi) Declared Values
vii) Date of Start of Testing
viii) Date of completion of testing
ix) Result
x) Remarks

Details of Sample drawn for Independent testing, if applicable. (Enclose separate test request for each product)
Discussion with the firm on Inspection and Testing Plan and Certification Fee
Non-Conformities, if any:

Section-4: Conformity of Process requirements

Enclose Checklists for Conformity of Process requirements at different stages					
Compliance percentage					
Avg scores of areas→	Co-operative society	Bulk Milk Cooling Centre	Milk Chilling Centre	Dairy Unit	
Critical (100%)					
Major (Min 85%)					
Minor (Min 70%)					
Non-Conformities, if any:					

Section-5: Conformity to Management System Requirement

Summary of Audit Process
Observations on reliability of internal audit and effectiveness of Management Review
Whether audit objectives have been accomplished within audit scope in accordance with audit plan?

Any areas not covered, although within the audit scope.
Any unresolved diverging opinions between audit team and auditee.
Audit preparation details , reference to checklist and sectoral guidelines, if any (<i>record briefing of team members by the expert about the technical aspects and applicable regulatory requirements. Also record identification of requirements to be audited by expert in Audit Plan Matrix by the expert</i>):
Audit Plan Matrix (<i>Attach MSC-F6.4-36, duly filled-in with processes/departments specified, with identification of requirements to be audited with an expert</i>)
Observation Sheet, Opportunity for improvement, Assessment of regulatory requirements and Expert's Report (<i>Attach MSC-F6.2-10 and others as applicable</i>)
Non-Conformities, if any:

Section 6– Summary Of Findings

Non-conformities (<i>Data on NCs raised against Clause/Sub-clause of standard(s) against which firm was audited</i>)			
Major NC :			
Minor NC :			
Opportunity for Improvement :			
Review Previous Audit Findings, if applicable: Verification of actions taken by firm on nonconformities pending from surveillance/other audit (<i>for recertification audit</i>) and pending points from Stage 1 audit (<i>for certification audit</i>)			
Date of NC/Points Raised	Clause of IS/ISO	Action taken	Current Status
Audit conclusions and recommendations of audit team			

	ANNEXURES	Page No
a)	Audit Plan	
b)	Audit Matrix (MSC-F6.4-36)	
c)	Confidentiality report	
d)	Letter for Scope of Certification, if applicable	
e)	Report of action taken on previous audit findings, if any	
f)	Audit observations (MSC-F6.2-10)	
g)	Report of Expert, if applicable	
h)	Non-conformity Reports (MSC-F6.4-14)	
i)	Opportunity for Improvement (MSC-F6.2-10)	
j)	Audit Report submitted to auditee (MSC-F6.4-44)	
k)	Audit Log Sheet (MSC-F7.1-04)	
l)	Performance evaluation reports, if applicable MSC-F7.4-01	
m)	Participants of Opening and Closing meeting	
n)	Process Checklists for Stage 2 audit	
o)	Factory Test Reports(s)	
p)	Test Request (s)	

Signatures of Audit Team:

Name and Designation

मानक: पथप्रदर्शक:

Template for Factory Test Report

- i) Name of Product
- ii) IS Number
- iii) Variety
- iv) Batch Number/Lot Number
- v) Date of Manufacturing
- vi) Best Before/ Shelf Life
- vii) Declared Values
- viii) Date of Start of Testing
- ix) Date of completion of testing

S.No.	Parameter	Test Method ref	Requirement	Result	Remarks

Signature of Testing Personnel:

Signature of Lab In-charge:

Signature of Auditor:

मानक: पथप्रदर्शकः

**CHEKLIST OF PROCESS REQUIREMENTS TO BE VERIFIED DURING
STAGE 2 AUDIT**

FORMAT FOR MILK COLLECTION CENTERS/ COOPERATIVE SOCIETY

Name of the Centre/ Society:

Address/ Location:

Date of Visit:

S. No.	General Information	Remarks
1	FSSAI registration no. & Year of inception	
2	Present milk procurement per day	
3	Avg. Milk Fat and SNF	
4	Milk Collection timing: Morning & Evening	

Sl. No.	Requirement	Category	Satisfactory/ Unsatisfactory)	Remarks (briefly describe how requirement is met or not)
1.0	Location & Surroundings			
1.1	Is surroundings of clean, free from waste, water logging etc.	Major		
2.0	Infrastructure and facility			
2.1	Is the facility having pucca building and maintained in good condition	Major		
2.2	Is housekeeping and cleaning satisfactory	Major		
2.3	Is floor maintained neat and clean	Major		
2.4	Are adequate milk accessories available?	Minor		
2.5	Is sufficient washing facility available for cans, utensils, sampling & testing accessories	Major		
2.6	Is there adequate natural and/ or artificial lighting , covered and at appropriate location	Major		
3.0	Practices			
3.1	Is milk collection timing displayed	Minor		
3.2	Are producers bringing milk in Stainless steel	Major		
3.3	Are milk vessels bringing by producers properly covered	Major		
3.4	Is any foreign matter (flies, straw, dung etc.) present in raw milk coming to the DCS	Critical		
3.5	Is milk filtered properly through strainer	Critical		
3.6	Is milk tested for presence of any adulterants	Critical		
3.7	Does the DCS maintain fat and SNF records	Minor		
3.8	Are personal Hygiene practices followed at DCS	Major		
3.9	Are the milk handlers are free from cuts/wounds on their hands	Major		
3.10	Is the tester is trained on analysis	Major		
3.11	Are the CMP and GMP activities undertaken by the DCS to farmers	Major		

3.12	Are cattle feed being stored in separate rooms	Minor		
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SI No	Parameter	Total Points	Compliance	% Compliance	Remark
1	Critical	3			
2	Major	12			
3	Minor	4			
		19			



PROCESS REQUIREMENTS TO BE VERIFIED DURING STAGE 2 AUDIT

FORMAT FOR BULK MILK COOLING CENTRE (BMC)

Name of BMC:

BMC's Location / Address:

DATE OF VISIT _____

S. No.	General Information	Remarks
1	BMC FSSAI registration/ License no.	
2	Unit ISO Certification, if applicable	
3	Number and Capacity of BMC	
4	Single village based BMC or cluster BMC	
5	If Cluster, how many DCS attached	
6	Present milk procurement per day	
7	Average Milk Fat and SNF	

S. No	Requirement	Category	Observations (Satisfactory/ Unsatisfactory)	Remarks (briefly describe how requirement is met or not)
1.0	Infrastructure & facilities			
1.1	Is BMC unit located away from environmental contaminants (e.g. smoke, objectionable odor etc.)	Major		
1.2	Are the premises of the unit neat, clean and free / away from garbage or waste	Critical		
1.3	Is BMC center have pucca building, maintained in a sound condition and free from cobwebs, seepage	Major		
1.4	Are windows/ other opening properly covered with wire mesh of appropriate size	Major		
1.5	Are floors pucca and maintained in a sound condition, without damages, pot holes with accumulated water or water milk mix	Major		
1.6	Is there adequate space inside BMC room for performing routine operation and maintenance	Major		
1.7	Does the unit have adequate quantity of hot water for cleaning	Major		
1.8	Whether soak-pit for discharge of waste water available with the unit.	Major		
1.9	Is adequate sources of water available.	Major		
1.10	Do the Centre has adequate natural and/ or artificial lighting, covered and at appropriate location	Major		
2.0	Operation/ Practice			
2.1	Is milk collection timing displayed and followed	Minor		
2.2	Is milk collection completed within 2 hrs at BMC and within 3hrs for cluster BMC	Major		
2.3	Are producers bringing milk in Stainless steel	Major		
2.4	Are milk vessels bringing by producers properly covered	Major		
2.5	Is any foreign matter (flies, straw, dung etc.) present in raw milk coming to the centre	Critical		
2.6	Is milk filtered before loading to BMC tank	Critical		

2.7	Is milk chilled at desired temperature (4 °C), If yes whether maintained records for temperature	Critical		
2.8	Is appropriate remedial action taken when informed of problems identified during internal monitoring visit	Major		
2.9	Is standard operating procedure for cleaning of BMC tank available	Major		
2.10	Is BMC tank properly clean (outside and inside surface of the tank)	Critical		
2.11	Are proper cleaning agents available and effectively used	Major		
2.12	Is hosepipe and other milk pipelines are properly cleaned (to be physically verified)	Critical		
2.13	Is other milk collection accessories (weighing scale, sampling bottles, plunger etc.) properly cleaned	Major		
2.14	Are milk cans properly cleaned	Major		
2.15	Are cattle feed being stored in separate rooms	Minor		
2.16	Are pipelines dismantled and cleaned at specified frequencies (minimum twice in a week)	Major		
2.17	Does the unit display signboard with the following declaration? Such as No Smoking & No spitting	Minor		
3.0	Testing			
3.1	Are non-absorbent platform is available for testing	Major		
3.2	Are adulteration tests being carried out and recorded	Critical		
3.3	Does the BMC Centre maintain fat and SNF records	Minor		
3.4	Is testing chemicals identified and labelled properly	Minor		
4.0	Manpower, training and personal hygiene			
4.1	Is the tester is trained on analysis	Major		
4.2	Are the CMP and GMP activities undertaken by the DCS to farmers	Major		
4.3	Are personal Hygiene practices followed at DCS	Major		
4.4	Are the milk handlers are free from cuts/wounds on their hands	Major		

Sl No	Parameter	Total Points	Compliance	% Compliance	Remark
1	Critical	7			
2	Major	23			
3	Minor	5			
		35			

PROCESS REQUIREMENTS TO BE VERIFIED DURING STAGE 2 AUDIT

FORMAT FOR MILK CHILLING CENTRE (MCC)

Name of Milk Union/ Unit:

Name of MCC:

Address of the MCC:

Date of Inspection /Assessment:

S. No.	General Information	Remarks
1	Year of Inception	
2	MCC FSSAI registration/ License no.	
3	Unit ISO Certification, if applicable	
4	Capacity of MCC	
5	DCS/MPP attached	
6	Present milk procurement per day	
7	Average Milk Fat and SNF	

Sl. No.	Requirement	Category	Observations (Satisfactory/ Unsatisfactory)	Remarks (briefly describe how requirement is met or not)
1.0	General Information about technical personnel	Major		
1.1	Are adequate number of staffs available in the Milk Chilling Centre One DT/IDD, Lab. Assistant, Maintenance etc.,	Major		
2.0	Primary Production holding and raw milk collection			
2.1	Are the surfaces of milk contact vessels/utensils used by farmer/producer to bring milk to MCC washable and non-toxic (preferably SS – AISI 304)	Major		
2.2	Are the samples of water drawn for testing /analysis to ascertain safety to human health and records maintained.	Major		
2.3	Is there adequate protection from contamination from pests /insects /animals /environment at MCC	Major		
2.4	Do persons performing / handling of raw milk wear suitable clean clothes and maintain high degree of personal hygiene	Major		
2.5	Are there suitable facilities for cleaning/ washing of hands and collection equipment	Major		
3.0	Premises of MCC			
3.1	Is the premises boundary properly constructed to prevent entry of animals etc	Major		
3.2	Are roads -around the building- concreted or tarred or turfed	Major		
3.3	Is the building premises free from swamps, stagnated water, dumps	Critical		
3.4	Is the process building protected from entry of animals , pets etc	Critical		
3.5	Is the building protected /away from environmental contaminants e.g., smoke,	Critical		

	objectionable odours, dust, etc			
3.6	Are the refuse collecting containers of self-closing type and located at strategic locations	Major		
4.0	Layout, design, construction, location and size of MCC:			
4.1	Does it permit good food hygiene practices, including pest control, insect etc	Critical		
4.2	Is it kept clean and maintained in good repair and condition	Major		
5.0	Lavatories/Toilets			
5.1	Are there adequate number of flush lavatories available and connected to an effective drainage system	Major		
5.2	Do the sanitary conveniences /toilets have adequate natural or mechanical ventilation			
6	Washing facilities			
6.1	Are there an adequate number of washbasins available, suitably located and designated for cleaning hands at entry points	Major		
6.2	Are the washbasins for cleaning hands provided with detergent, disinfectant, etc and for hygienic drying e.g. dryers, single use towels.	Major		
7	Ventilation and lighting			
7.1	Is there suitable and sufficient means of natural or mechanical ventilation (sufficient exhaust fans)	Minor		
7.2	Are the ventilation systems so constructed as to enable filters and other parts requiring cleaning or replacement, readily accessible	Minor		
7.3	Do the premises have adequate natural and/or artificial lighting	Minor		
7.4	Are the lights sufficiently protected/covered	Minor		
8	Drainage facilities			
8.1	Are these designed and constructed to avoid the risk of contamination to the food items	Major		
8.2	Are drainage channels properly covered as needed.	Major		
9	Building -General design and layout etc			
9.1	Does design and layout permit good food hygiene practices, including protection against contamination between and during operation	Major		
9.2	Is the general working environment in MCC suitable for hygienic and healthy operations - proper temperature , free of suffocation, without congestion/ cramping	Major		
10.0	Floors	Major		
10.1	Is material of construction proper - mandana in chilling area, CI tiles in reception etc	Major		
10.2	Are the floors maintained in a sound condition , without damages, pot holes with accumulated water/water milk mix	Major		
10.3	Is there water /water- milk mix accumulated on the floor due to slope/ poor	Major		

	cleaning			
11	Walls			
11.1	Are the surfaces maintained in a sound condition , free from cobwebs, seepage	Critical		
11.2	Is surface impervious, non-absorbent, washable and non-toxic material or appropriate to prevent contamination and does have a smooth surface up to a height (approx 6 feet)	Major		
12	Ceilings			
12.1	Is pucca ceiling provided in the entire milk chilling area	Major		
12.2	Is the height of ceiling proper to allow hygienic operations and non suffocating operations	Major		
12.3	Are the surfaces maintained in a sound condition , free from cobwebs, seepage, mould growth	Critical		
13	Windows /doors and other openings			
13.1	Are they constructed to prevent the accumulation of dirt	Major		
13.2	Are those, which can be opened to the outside environment, where necessary, fitted with insect-proof screens, which can be easily removed for cleaning	Major		
13.3	Are the doors easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	Major		
14	Surfaces (including surfaces of equipment)			
14.1	Are the outside surfaces of equipment, in general and in particular those which are in contact with milk/food , clean (free from dried milk marks/ dust etc).	Major		
14.2	Are these smooth, washable corrosion-resistant and non-toxic materials or appropriate preferably SS (AISI 304)to prevent contamination	Major		
15	Cleaning / Sanitization facilities			
15.1	Are adequate facilities provided, where necessary, for the cleaning, disinfecting of working utensils and equipment	Critical		
15.2	Are these facilities have an adequate supply of hot and cold water	Critical		
15.3	Are the cleaning agents and disinfectants stored separately under lock and key	Major		
15.4	Is the effectiveness of cleansing (absence of residual chemical) verified periodically through laboratory tests	Major		
16	Raw Milk Reception			
16.1	Is RMRD raised with sides and top sufficiently protected to prevent contamination while unloading of raw milk	Major		
16.2	Are air curtain / fly proof mesh provided to prevent entry of flies	Major		
16.3	Are in-line filters for raw milk available	Major		
16.4	Is the ceiling height (min 5.5 M) to prevent accumulation/condensation of	Major		

	moisture			
16.5	Is there proper ventilation to prevent suffocation in the raw milk reception area (can washer)	Major		
16.6	Are can washing operations proper (If cans scrubber is used- are the cans cleaned properly and if can washer is used- are the cans cleaned properly and coming out dry)	Major		
17	Chilling Section			
17.1	Is milk is chilled and stored below 4 °C and record kept	Critical		
18	Equipment			
18.1	Is the material of construction proper for milk handling/processing (preferably SS 304/316)	Critical		
18.2	Are the equipment kept in clean state and properly sanitized.	Critical		
18.3	Are these provided with proper recording instruments (temp /pressure/ flow rate)	Critical		
18.4	Are the process control equipment calibrated properly- proper records kept	Critical		
19	Water			
19.1	Is proper record of quality of Water used for the processing kept	Major		
19.2	If water obtained from external sources is tested/analysed and documented for its potability	Major		
19.3	Is water stored in over head storage tanks protected from outside contamination	Major		
19.4	Are such over head tanks easily accessible for cleaning; disinfection	Major		
19.5	Is there Cleaning schedule for water storage tanks/facilities available and followed properly (by records)	Major		
20	Effluent treatment systems			
20.1	Does the MCC have an working ETP	Observation on Effluent Treatment System must be recorded		
20.2	Is capacity of ETP sufficient to take care of total load.			
20.3	Does the discharged effluent comply with the statutory requirements in force (BOD, COD, etc)			
20.1	Is smell observed near the ETP			
21	Maintenance/Calibration schedules			
21.1	Is there a documented procedure for the maintenance of different sections of the dairy/ equipment/ plant and machinery/ laboratory items	Major		
21.2	Is there a documented procedure for the calibration of instruments/gauges/ in different sections i.e. Engineering, Processing and laboratory	Major		
22	Quality Assurance systems and Laboratory Procedures			
22.1	Are the certified QA systems of ISO and HACCP/FSMS (ISO-HACCP - IS 15000/ ISO 22000/FSSC 22000) in place	Minor		
22.2	Are the breakdowns /malfunctions/ Product failure recorded and proper traceability	Major		

	system in place			
22.3	Is there proper arrangement for pest & vermin control and documented procedure is maintained (either by self or through outside agency)?	Critical		
22.4	Is laboratory in good condition , having shelf / working table with acid resistant tiles in acid handling area	Major		
22.5	Are proper facilities there for chemical and MBRT analysis	Major		
22.6	Are personnel responsible for conducting microbiological and chemical analysis properly qualified/trained	Major		
22.7	Is proper testing done on as per the SOP	Major		
23	Personnel health and hygiene			
23.1	Are the persons in milk process plant follow hygienic practices (as per the observation of team)	Major		
23.2	Is there daily hygiene checks and record maintained	Major		
23.3	Whether there are arrangements for change of footwear / foot dip / foot cover provided	Major		

SI No	Parameter	Total Points	Compliance	% Compliance	Remark
1	Critical	14			
2	Major	52			
3	Minor	5			
		71			

मानक: पथप्रदर्शक:

PROCESS REQUIREMENTS TO BE VERIFIED DURING STAGE 2 AUDIT

CHECKLIST FOR DAIRY UNIT

Name of Processing Establishment:

Address of the processing establishment:

Date of Inspection /Assessment:

S. No.	Requirement	Category	Observations (Satisfactory/Unsatisfactory)	Remarks (briefly describe how requirement is met or not)
1	General Information about technical personnel			
1.1	Are adequate number of Technologists available in the establishment	Major		
1.2	Are adequate Number of Veterinarians available for handling quality and food safety aspects in Primary Production area.	Major		
1.3	Are personnel for developing, implementing and maintaining HACCP-based procedures adequately qualified and experienced.	Critical		
1.4	Are sufficient number of supervisors/persons available (apart from the above), responsible for processing and maintenance of sanitation and hygiene in the establishment separately.	Major		
2	Primary Production holding and raw milk collection			
2.1	Whether the establishment have records to support the backward traceability.	Critical		
2.2	Are training programme organized by union/unit / through external agency for producers for CMP etc at regular interval - supported by records/documents	Critical		
2.3	Are effective steps taken by the unit (education/training to producers) to prevent use of prohibited antibiotics/pharmacological substances and Chemicals at the primary production holdings.	Critical		
2.4	Are the samples (feed, water) drawn for testing/analysis to ascertain safety to human health and records maintained.	Major		
2.5	Is appropriate remedial action taken when informed of problems identified during audits/checks/routine monitoring - supported by records	Major		
2.6	Are there suitable facilities for cleaning/ washing of hands and collection equipment	Major		
3	Premises of Unit			

3.1	Is the premises boundary properly constructed to prevent entry of animals etc.	Major		
3.2	Are roads -around the building- concreted or tarred or turfed?	Major		
3.3	Is the building premises free from swamps, stagnated water, dumps?	Critical		
3.4	Is the process building protected from entry of animals , pets etc	Critical		
3.5	Is the building protected /away from environmental contaminants e.g., smoke, objectionable odours, dust, etc.?	Critical		
3.6	Are the refuge collecting containers of self-closing type and located at strategic locations	Major		
4	Layout, design, construction, location and size of processing premises:			
4.1	Does it permit good food hygiene practices, including pest control, insect etc	Critical		
4.2	Is it kept clean and maintained in good repair and condition?	Major		
5	Lavatories/Toilets			
5.1	Are there adequate number of flush lavatories	Major		
5.2	available and connected to an effective drainage system?	Critical		
5.3	Do Exhaust and door of lavatories open directly into rooms in which food is handled?	Major		
5.4	Do the sanitary conveniences /toilets have adequate natural or mechanical ventilation .	Major		
5.5	Is there system to prevent exhaust from toilets etc to process hall or any food handling place to avoid entry of contaminated air.	Major		
6	Washing facilities			
6.1	Are there an adequate number of washbasins available, suitably located and designated for cleaning hands at all entry points to the food handling areas?	Major		
6.2	Are the washbasins for cleaning hands provided with detergent, disinfectant, etc. and for hygienic drying e.g. dryers, single use towels?	Major		
6.3	Are foot disinfections facilities like foot dip provided, wherever applicable?	Major		
7	Ventilation and lighting			
7.1	Is there suitable and sufficient means of natural or mechanical ventilation (sufficient exhaust fans)?	Minor		
7.2	Is there set up to prevent mechanical airflow from a contaminated area / external area to a clean area (process halls)	Major		
7.3	Are the ventilation systems so constructed as to enable filters and other parts requiring cleaning or replacement, readily accessible?	Minor		
7.4	Do the premises have adequate natural and/or artificial lighting?	Minor		
7.5	Are the lights sufficiently protected/covered?	Minor		
8	Drainage facilities			
8.1	Are these designed and constructed to avoid the risk of contamination to the food items	Major		
8.2	Are drainage channels properly covered as needed?	Major		
9	Change room facilities			

9.1	Are adequate changing facilities (change room and facilities therein), provided for personnel handling raw material, unprocessed products and processed products?	Critical		
9.2	Is there separate facility for male and female workers?	Minor		
9.3	Whether changing room facility is properly located i.e., integrated into the plant layout properly or if away whether provided with pucca road to prevent contamination from dust/dirt etc after worker leaves change room and enters process area.	Major		
9.4	Does the changing room have proper facilities - smooth walls, floors and washbasins with soaps, disposable towels and non-hand operable taps?	Major		
9.5	Whether there are arrangements for Change of footwear, Keeping street clothes separately, Lockable cupboards	Major		
9.6	Is there suitable in-house/outside arrangement to launder the working clothes of the workers?	Major		
10	Process Hall -General design and layout etc			
10.1	Does design and layout permit good food hygiene practices, including protection against contamination between and during operations	Major		
10.2	Is the general working environment in process hall/ packing rooms suitable for hygienic and healthy operations - proper temperature, free of suffocation, without congestion/ cramping?	Major		
11	Floors			
11.1	Is material of construction proper - mandana in process area, CI tiles in reception, kota stone / polycrrete etc in lab	Major		
11.2	Are the floors maintained in a sound condition, without damages, pot holes with accumulated water/water milk mix?	Major		
11.3	Is there water /water- milk mix accumulated on the floor due to slope/ poor cleaning.	Major		
12	Walls			
12.1	Are the surfaces maintained in a sound condition , free from cobwebs, seepage	Critical		
12.2	Is surface impervious, non-absorbent, washable and non-toxic material or appropriate to prevent contamination and does have a smooth surface up to a height (approx 6 feet)?	Major		
12.3	Are there suitable arrangements (SS railing/cladding) to protect damage to walls by equipment and other items (trolleys etc)	Major		
13	Ceilings			
13.1	Is pucca ceiling provided in the entire milk processing area	Major		
13.2	Is the height of ceiling proper to allow hygienic operations and non-suffocating operations(approx5.5 mts)	Major		
13.3	Are the surfaces maintained in a sound condition , free from cobwebs, seepage, mould growth	Critical		
14	Windows /doors and other openings			

14.1	Are those, which can be opened to the outside environment, where necessary, fitted with insect-proof screens, which can be easily removed for cleaning?	Major		
14.2	Are, where open windows would result in contamination, kept closed during production?	Major		
14.3	Are the doors easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	Major		
14.4	Are doors provided with automatic door closures	Major		
14.5	Are the doors provided with suitable air curtain/other arrangements to prevent entry of air when opened to prevent contamination	Major		
15	Surfaces (including surfaces of equipment)			
15.1	Are the outside surfaces of equipment, in general and in particular those which are in contact with milk/food, clean (free from dried milk marks/dust etc).	Major		
15.2	Are these smooth, washable corrosion-resistant and non-toxic materials or appropriate preferably SS(AISI 304)to prevent contamination	Major		
16	Cleaning / sanitization facilities/centralized CIP			
16.1	Are adequate facilities provided for cleaning and disinfecting of working utensils and equipment, (Pipelines, Silo etc.)?	Critical		
16.2	Are these facilities have an adequate supply of hot and cold water?	Critical		
16.3	Are the cleaning agents and disinfectants stored separately under lock and key?	Major		
16.4	Is Centralized CIP System available? If Yes, whether of suitable capacity	Major		
16.5	Are the auto-controls working (timers, temperature controllers, valves)?	Major		
16.6	Is the effectiveness of cleansing (absence of residual chemical and swab/rinse test) verified periodically?	Major		
17	Plant Facilities			
17.1	Are there Separate storage facilities for edible, non- edible constituents (fuel/cleaning agents etc).	Major		
17.2	Are there Separate storage for wet and dry items	Major		
17.3	All the gauges, temperature including spares properly calibrated and in working order.	Critical		
18	Raw Milk Reception			
18.1	Is RMRD raised with sides and top sufficiently protected to prevent contamination while unloading of raw milk?	Major		
18.2	Are air curtain / fly proof mesh provided to prevent entry of flies	Major		
18.3	Are in-line filters for raw milk available?	Major		
18.4	Is the ceiling height (min 5.5 M) to prevent accumulation/condensation of moisture	Major		
18.5	Is there proper ventilation to prevent suffocation in the raw milk reception area (can washer)	Major		
18.6	Are can washing operations proper (If cans scrubber is used- are the cans cleaned properly and if can washer is used- are the cans cleaned properly and coming out dry)	Major		

18.7	Are proper arrangements in place for cleaning, sanitisation of road milk tankers bringing chilled milk to processing unit	Major		
18.8	Are Tanker cleaning facilities so designed to prevent contamination of fresh raw milk /food from water (after cleaning) , detergents etc	Major		
19	Processing Section			
19.1	Are the entrances so designed to prevent entry of flies	Major		
19.2	Is the system there so that Pasteurization Temperature and holding time of milk. (ideally 72°C for 15 seconds for HTST) properly maintained			
19.3	Is FDV provided and whether working properly Are the facilities so designed to stop falling of	Critical		
19.4	Water/water- milk mix (from equipment/working tables) directly on the floor (e.g., being drained through pipe).	Major		
20	Equipment			
20.1	Is the material of construction proper for milk handling/processing (preferably SS 304/316)	Critical		
20.2	Are the equipment kept in clean state and properly sanitized.	Critical		
20.3	Are these provided with proper recording instruments(temp /pressure/ flow rate)	Critical		
20.4	Are the process control equipment calibrated properly- proper records kept	Critical		
21	Food Waste/ refuse			
21.1	Are edible/ non edible By Products / waste food items removed quickly to prevent contamination?	Major		
21.2	Are edible/ non edible By Products / waste food items after removal kept at a faraway place to prevent contamination?	Major		
21.3	Are the refuse storage areas free of animals, pets and pests?	Major		
21.4	Is the refuse handled in a hygienic manner as per the guidelines of pollution control deptt and also does not cause contamination to the processing area.	Major		
22	Water			
22.1	Is proper record of quality of Water used for the processing kept?	Critical		
22.2	If water obtained from external sources is tested/analyzed and documented for its potability.	Major		
22.3	Does the dairy have water softening and water disinfection plant (if needed)	Major		
22.4	Is capacity of facility (softener/disinfection sufficient for operations	Major		
22.5	Is water stored in overhead storage tanks protected from outside contamination?	Major		
22.6	Are such overhead tanks easily accessible for cleaning; disinfection.	Major		
22.7	Is there Cleaning schedule for water storage tanks/facilities available and followed properly (by records)	Major		
22.8	Is quality water (IS 4251) availability sufficient in relation to maximum daily production?	Major		

23	Freezing/Cold Store Systems			
23.1	Is there appropriate schedule for Maintenance, cleaning and disinfection of freezers/cold stores	Major		
23.2	Is the temperature of the freezers/ cold store recorded? If so, are the recording equipment calibrated and certified?	Critical		
23.3	Is Documentation of recordings of temperatures of the freezers/cold store available	Major		
23.4	Is the area of cold rooms sufficient for proper storage of milk and milk products (400 Lts/m2)	Major		
23.5	Is there proper ante room / air lock or suitable working arrangements?	Minor		
23.6	Are the pallets made of non-absorbent materials (other than wood)?	Major		
24	Packaging film, Packaging, pouch, crates and Storage			
24.1	Is the packaging film made from virgin material.	Critical		
24.2	Is the film material fit (food grade) for use for food items/milk and milk products	Critical		
24.3	Is there any instance of printing ink coming off the film and getting transferred to inside of film in rolls.	Critical		
24.4	Is the printing from ink approved for use for milk and milk products packet.	Major		
24.5	Is the film of proper thickness required for leak proof/ sturdy packing	Major		
24.6	Does the print matter broadly comply with the requirements of labelling requirement (such as FSSAI licence number, type of product, use before date etc) – as regards full compliance the unit is responsible.	Critical		
24.7	Packaging area well protected from rodents and pests	Critical		
24.8	Is the packing room hygienically maintained and free from waste film etc	Major		
24.9	Is the packaging material reused?	Critical		
24.10	Are the packed units randomly weighed (for total weight of product and packaging material) and records maintained	Critical		
24.11	Is the temp of packed product checked periodically and records maintained	Minor		
24.12	Are the crates of milk pouches in sound condition- without cracks, broken etc	Major		
24.13	Are the crates of milk pouches properly cleaned	Major		
24.14	Are the UV tube lights of packing machines working			
24.15	Is there proper system for traceability in place	Critical		
24.16	Is there facility to store day stock packaging materials in safe and hygienic manner	Critical		
24.17	Is there proper facility to store primary / secondary / tertiary packaging materials in hygienic and dust free environment	Major		
25	Steam and Air Supply and Effluent treatment systems			
25.1	When steam / air comes in direct contact with food or food contact surfaces, is it free from substances that may (i) be hazardous to health (ii) contaminate the milk / milk products (iii) Free from oil or other such material	Critical		

25.2	Does the dairy have a working ETP?	Major		
25.3	Is capacity of ETP sufficient to take care of total load	Major		
25.4	Does the discharged effluent comply with the statutory requirements in force (BOD, COD, etc)?	Critical		
25.5	Is smell observed near the ETP	Major		
26	Maintenance/Calibration schedules			
26.1	Is there a documented procedure for the maintenance of different sections of the dairy/ equipment/ plant and machinery/ laboratory items	Major		
26.2	Is there a documented procedure for the calibration of instruments/gauges/ in different sections i.e. Engineering, Processing and laboratory	Major		
27	Quality Assurance systems and Laboratory Procedures			
27.1	Are the certified QA systems of ISO and HACCP/FSMS (ISO-HACCP - IS 15000/ ISO22000/FSSC 22000) in place?	Critical		
27.2	Are the breakdowns /malfunctions/ Product failure recorded and proper traceability system in place?	Major		
27.3	Is there proper arrangement for pest & vermin control and documented procedure is maintained? (either by self or through outside agency)?	Critical		
27.4	Is there a separate laboratory (away from main building) for pathogen testing or alternatively, pathogen testing are being done at outside labs at regular intervals	Critical		
27.5	Is laboratory in good condition, having shelf /working table with acid resistant tiles in acid handling area.	Major		
27.6	Is working area on shelf / working table in good condition- not affected by acid.	Major		
27.7	Are proper facilities there for compositional and chemical analysis	Critical		
27.8	Are proper facilities available for Microbial testing/ analysis	Critical		
27.9	Are personnel responsible for conducting microbiological and chemical analysis properly qualified/trained?	Major		
27.10	Are the proper sampling procedures followed for testing of raw material, in process and finished goods?	Major		
27.11	Is proper testing done on raw materials (microbial contaminants, chemical contaminants and residues) / Raw milk (Somatic Cell Counts, Chemical contaminants and residues) and records maintained?	Major		
27.12	Is proper testing done in process materials and records maintained?	Major		
27.13	Is proper testing done on finished goods and records maintained?	Major		
28	Personnel health and hygiene			

28.1	Is the health of person employed in processing section, milk products manufacturing packaging handling checked regularly so that they are disease free and fit to work in milk and milk products unit health records verification.	Critical		
28.2	Is there any system/mechanism in place for checking hygiene and cleanliness of operators/workers on daily basis- supported by records/ documents?	Critical		
28.3	Are the person in milk process plant follow hygienic practices (as per the observation of team)	Critical		
28.4	Is there a system to prevent any other person (from other departments) suffering from contagious disease, open cuts wounds etc- coming in close proximity of milk processing / products handling area.	Critical		
29	Transport vehicles for distribution			
29.1	Is the vehicle kept in a clean condition	Critical		
29.2	Are all the vehicles used for distant places (say more than 30 km) insulated and covered	Major		
29.3	Are Vehicles used within city or up to 30kms insulated or properly	Major		
30	Retails Outlets/ Points			
30.1	Is the establishment owned)Both or parlour) or leased retail outlet has hygienic surrounding (free from garbage away from open drain etc)	Major		
30.2	Is the general hygiene inside the premises satisfactory	Major		
30.3	Are the inside walls ceiling etc free of cobwebs	Minor		
30.4	Is the personal hygiene of retailer OK/proper	Minor		
30.5	In case of temporary/ make shift retail out for liquid milk. Is any shade provided over crates and milk pouches?	Major		
30.6	Are there adequate cooling chilling facilities(refrigerator, digicooler) with the retailer to keep unsold milk of one shift	Major		
30.7	Is the behavior of retailers with costumers courteous and respectful	Minor		
31	General feedback from customers			
31.1	Does the establishment have proper and easy system to receive and resolve consumer complaints (Email other than one with conditionality's through web site link, responsive telephone no)	Critical		

Sl No	Parameter	Total Points	Compliance	% Compliance	Remark
1	Critical	45			
2	Major	96			
3	Minor	10			
		157			

LICENCE DOCUMENT

फॉर्म II (स्कीम IX के पैराग्राफ 3 के उप-पैरा (5) का खंड (ए) देखें)
Form II (Refer clause (a) of sub-paragraph (5) of paragraph 3 of Scheme IX)



भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS LICENCE FOR CONFORMITY ASSESSMENT SCHEME FOR MILK AND MILK PRODUCTS



Licence for certification of compliance to Food Safety Management system,
Process requirements and Milk Products listed in the Schedule to this licence
[Accredited by NABCB for FSMS]

Licence no.

By virtue of the power conferred on it by, the Bureau of Indian Standards Act, 2016 (11 of 2016), the Bureau hereby grants/recertifies to (hereinafter called the licensee) the right and licence to be listed in the Bureau's list(s) of licensee as per Scheme - IX for Management System(s), Process requirements and Product(s) described in the schedule hereto, bearing the same number as this licence.

Such product(s)/service(s)/process(es) shall be manufactured/provided/carried by the licensee at only the address(es) and in accordance with the Standard(s)/requirements given in the schedule of this certificate.

The licence is granted/recertified subject to the relevant provisions of the above Act and the rules and regulations made thereunder governing the licence referred to above, and the licensee hereby covenants with the Bureau duly to observe with the said Act, Rules and Regulations.

This licence shall be valid from to and may be recertified as prescribed in the regulations.

Signed, Sealed and Dated this day of

मानक: पथप्रदर्शक:

For Bureau of Indian Standards
Name and Signature of Designated authority

CONFORMITY ASSESSMENT SCHEME FOR MILK AND MILK PRODUCTS

फॉर्म II (स्कीम IX के पैराग्राफ 3 के उप-पैरा (5) का खंड (ए) देखें)
Form II (Refer clause (a) of sub-paragraph (5) of paragraph 3 of Scheme IX)



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
LICENCE FOR CONFORMITY ASSESSMENT SCHEME FOR
MILK AND MILK PRODUCTS



Licence for certification of compliance to Food Safety Management system,
Process requirements and Milk Products listed in the Schedule to this licence
[Accredited by NABCB for FSMS]

Schedule to licence no.

Issued to:

for compliance of Management system(s) as per Indian Standard(s)
..... and process requirements for the Product(s) as
follows:

Sr. No.	Specifications	Product	Variety/Type/Grade etc.
(i)			
(ii)			
(iii)			
(iv)			

Signed, Sealed and Dated this day of month of year

मानक: पथप्रदर्शक:

For Bureau of Indian Standards

Name and Signature of Designated authority

CONFORMITY ASSESSMENT SCHEME FOR MILK AND MILK PRODUCTS

GUIDELINES FOR AUDIT TIME CALCULATION FOR CONFORMITY ASSESSMENT OF MILK AND MILK PRODUCTS

1.0 Purpose- Guidelines for calculation of audit duration for conducting Stage-2/ Surveillance/
Re-certification audit for Conformity Assessment Scheme for Milk and Milk Products

2.0 Scope- Audit of Conformity Assessment Scheme for milk and milk products

3.0 Definition-

3.1 Audit time – Time needed to plan and accomplish a complete and effective audit of the organization's management system. Audit time includes total time on-site and the time spent off-site carrying out planning, document review, interacting with client personnel and report writing.

3.2 Audit duration- Part of audit time actually spent for conducting audit activities from opening to closing meeting. Audit duration should not be less than 80% of the audit time.

3.3 Audit Day- An audit manday is normally 480 minutes (8 hours) which may include time for lunch and tea breaks, if any.

3.4 Effective number of personnel- The effective number of personnel consists of all personnel involved within the scope of certification. It shall also include non-permanent and part time personnel.

4.0 General Considerations-

4.1 The effective number of personnel is used as a basis for calculation of audit duration for food safety management systems audit.

4.2 Factory testing time forms basis for calculation of audit duration for product certification audit.

5.0 Audit Time for Initial Certification Audit

5.1 Audit Time for Food Safety Management System Audit (A)

5.1.1 Calculation of total audit time for Stage 1 and Stage 2 audit for a single site, T_s

$$T_s = (1.5 + T_H + T_{FTE})$$

Where,

T_H is the number of audit days for additional HACCP studies and is calculated using the following formula:

$$T_H = 0.5 * \text{Number of additional HACCP study}$$

T_{FTE} is the number of audit days per number of personnel.

Add 0.25 mandays if management system implemented by the organization is not certified

Number of audit days per number of personnel (T_{FTE})

Number of Personnel	Mandays required
1 to 19	0
20 to 49	0.5
50 to 79	1.0
80 to 199	1.5

200 to 499	2.0
500 to 899	2.5
900 to 1299	3.0
1300 to 1699	3.5
1700 to 2999	4.0
3000 to 5000	4.5
> 5000	5.0

5.1.2 40% of the audit time calculated shall be utilized for Stage 1 audit subject to minimum of 2 mandays. In case the unit is holding FSMS from another CB, Stage 1 audit may be carried out for 1 manday.

Note: Any part of FSMS audited during Stage 1 audit may not be re-audited during the Stage 2 audit. However, the audit report of Stage 2 audit shall confirm that the already audited parts of FSMS continue to confirm to the requirements.

5.1.3 Audit time for Stage -2 audit of Food Safety Management System, **A:**

$$A = T_s - \text{Time for Stage 1 audit}$$

5.2 Audit Time for Product Certification (B)

5.2.1 Calculate time required for factory testing of each product individually, wherever Factory testing is required:

Product	IS	Complete Factory testing required (Y/ N)	Mandays required for factory testing

Audit Time for Product Certification (B) = Total time required for factory testing.

5.3 Audit Duration for Process requirements (C):

5.3.1 Audit duration for Visit to BMC/ VMC/ MCC sites: In situations where the certification scope includes these sites, an audit of each site shall be carried out. 0.25 mandays (02 working hours) for each site excluding time spent for travel. Whenever calculated audit time is a decimal number, the audit time shall be rounded upwards to the nearest half day (eg. 5.2 days becomes 5.5).

5.3.2 Audit duration for Dairy unit: In most cases the audit duration calculated for FSMS audit shall be sufficient to assess conformity to the process requirements in the dairy plant. However, in cases where relaxation is permitted in FSMS mandays, additional 2 mandays may be allotted for process requirements.

5.3.3 Audit duration for Process Requirements (C) = Total Time required for verification of 5.3.1 and 5.3.2

5.4 Total Time required for Stage 2 audit for conformity assessment of milk and milk products = (A) + (B) + (C)

6.0 Audit Time for Surveillance and recertification audits

- a) Audit time for Surveillance audit shall be one-third of the time required for auditing Food Safety Management systems (Ts), with a minimum of 2 mandays.
- b) Audit time for Re-certification audit shall be two-third of the time required for auditing Food Safety Management systems (Ts).



मानकः पथप्रदर्शकः

GUIDELINES ON CRITERIA FOR COMPETENCE FOR CONFORMITY ASSESSMENT SCHEME FOR MILK AND MILK PRODUCTS

1. PURPOSE

To ensure that all certification personnel selected for Conformity Assessment Scheme for Milk and Milk Products meet uniform criteria as set out in these guidelines.

2. SCOPE

These guidelines provide the criteria for competence required by auditors, technical experts, technical reviewers and decision makers of conformity assessment scheme for milk and milk products.

5. COMPETENCE CRITERIA

5.1 The various categories of personnel involved in certification are

- i) MSC Officer (Region) involved in Application review and Audit team selection;
- ii) Auditors including team leaders (both internal and external) involved in audit planning and auditing activities;
- iii) Technical Reviewer to review audit reports before decision is taken. The Technical reviewer can be a Team Leader/ Expert/ or any other personnel meeting the desired competence requirement; and
- iv) DDG (Region) and DDG –incharge of MSC activity at HQ who is the decision maker.

Competency requirements for personnel involved in various functions of FSMS Certification are classified into two types: Generic competency requirement and Specific competency requirement.

5.2 Generic competency requirements

The generic competency requirements for the personnel applicable in general for all management system schemes as given under MSC-G7.1-01 (for BIS Personnel) and MSC-G7.3-01 (for External Auditors) shall be complied with.

5.3 Specific competency requirements

Personnel involved in various functions of FSMS Certification shall meet the following criteria in order to acquire desired knowledge and skill requirements:

Auditor/ Technical Reviewers

- a) Degree in Engineering or Technology or post graduate course in Food Technology/ Dairy Technology/ Chemical Engineering/Agricultural Engineering/Veterinary Science /Food Micro-biology/ Food & Nutrition/ Chemistry/ Micro-biology /Agriculture or any other allied discipline.
- b) Successful Completion of Lead Auditor Course in FSMS.

- c) At least two year's work experience in dairy sector or any industry in the food chain (related to food safety functions or quality assurance or manufacturing, retailing, inspection or enforcement) or at least 20 mandays inspections of milk and milk products.

Experts

- a) Degree in Food Technology/ Dairy Technology/ Chemical Engineering/ /Agricultural Engineering/ Veterinary Science or any other related discipline or Post Graduate Degree in Food Technology/ Dairy Technology/Food Micro-biology/ Food & Nutrition/ Chemistry/ Micro-biology /Agriculture or any other related discipline.
- b) At least four years work experience in dairy sector or any industry in the food chain (related to food safety functions or quality assurance or manufacturing, retailing, inspection or enforcement) or at least 50 mandays inspections/audits of milk and milk products; or Consultancy activity for atleast two organizations for establishing FSMS/HACCP system in the dairy sector; or a Suitable combination of above.

Application Reviewer (MSCOR)

- a) Degree in Engineering or Technology or Post Graduate Degree in Science discipline with 3 years of work experience in BIS.
- b) Successful Completion of Lead Auditor course in FSMS or QMS.
- c) Basic understanding of Food safety/ HACCP/ FSMS through training or self-study.

Decision Maker (DDGR/ DDGMSC)

- a) Degree in Engineering or Technology or Post Graduate Degree in Science discipline with 15 years of work experience in BIS.
- b) Successful Completion of Lead Auditor course in FSMS or QMS.
- c) Basic understanding of Food safety/ HACCP/ FSMS through training or self-study.

5.4 Demonstration and evaluation of ability

5.4.1 In addition to above, auditors engaged in auditing activities, are required to demonstrate their ability to apply the knowledge and skills. The evaluation of the knowledge and skills of auditors is ensured as per the criteria and methods described in document MSC-G7.1-01.

Fee Structure for Certification Scheme for Milk and Milk Products

1. Application fee

₹ 1,000/-

2. Audit Fee: (for initial, re-certification and special audit)

(a) For units located within India:

(i) Large Industrial Enterprises- ₹. 12,000/- per manday

(ii) Micro, Small and Medium Industrial Enterprises- ₹. 9,000/- per manday

Travel limited to a distance of 250 km from the location of the unit and stay of auditors on actual basis shall be borne by the manufacturer.

Relaxation in audit fee: If the Actual Travel Cost incurred during an audit is less, the DDGR's may grant relaxation upto ₹ 4,000/- per manday spent in travelling for Large Industrial Enterprises and ₹3,000/- per manday spent in travelling for MSME enterprises.

(b) For units located outside India:

(i) ₹ 12,000/-per manday shall be chargeable.

(ii) The manufacturer shall bear all expenses on actual basis, including but not limited to cost to the Bureau for the man-days spent by auditor(s) in connection with the audit, resultant travel etc.

3. Certification Fee

The yearly certification fee shall as specified in Table-A of this Annexure.

Table-A

मानक: पथप्रदर्शकः

Sr. No.	Product category	Unit rate (in ₹)	Minimum certification fee large scale, per annum (in ₹)	Minimum certification fee Small and Medium Enterprises, per annum (in ₹)	Minimum certification fee Micro Enterprises, per annum (in ₹)
1.	Milk and milk products	3 per 1,000 litre for first 4,00,000 kilo-litres and 2 per 1,000 litres thereafter. (Liquid milk sold in case of liquid milk and Raw milk consumed in case of milk based products.	1,00,000	80,000	60,000

Note 1: – Classification of enterprises will be based on “The Micro, Small and Medium enterprises Development (MSMED) Act, 2006 (27 of 2006).”

Note 2: All the fees mentioned herein are exclusive of any taxes

मानक: पथप्रदर्शकः