SOP for inspection
PCPL/P/14

1.0. **PURPOSE:** The purpose of this procedure is to explain the Inspection procedure.

2.0. **SCOPE:** It Covers all activities of inspection of food establishments.

3.0. **RESPONSIBILITIES:** Technical Manager is responsible for this procedure.

4.0. DEFINITIONS

4.1. Inspection conducted as per schedule 4 of FSS Act as per Checklist of FSSAI.

5.0 Refrences:- ISO 17020: 2012, FSSAI TPA manual 2018

6.0 Procedure

1. **Pre Audit requirements:**

1.1 Inquiry: The client Inquiry is received by any mode.

1.2 Application form: The application form is sent to client.
PCPL also main information supplied by any other party as part of the inspection process, it is verify whether it is relevant or not and integrity of such informaction is maintain.

1.3 Application review: The application is reviewed for completeness, validity of FSSAI license/ registration, availability of mandatory Fostac training. Based on information in application form Audit time is arrived (**based on Table1 for manufacturing covered in IAF code-03 and Table2 for catering covered in IAF code-30**) and accordingly basic quotation is arrived.

1.4 Quotation: The quotation is sent to client physically or electronically

1.5 Contract agreement for TPA: Contract agreement will be signed by the Client and PCPL.
PCPL is enclosing the Form C (Annexure 3) of FSSAI auditing regulation 2018 with this Agreement before the commencement of the audit.

1.6 Appointment of auditor: auditor appointment is done as per the availability and sector approval. Impartiality and confidentiality is signed with client at the time of audit.

1.7 Audit programme: audit programme is prepared and auditor selection is done, and client acceptance is taken for the audit date.

1.8 Audit Plan: Audit plan is prepared either by the Technical Manager / Auditor for the detailed schedule of audit and send to the client at least 8 days in advance from the date of audit. TPA audit will be the ON-SITE audit as per the man day calculation. Audit will not be conducted as surprise audit unless specified by the food authority. Audit plan should include the reporting time, audit duration starting time and ending time, audit scope, objectives, criteria, (i.e Schedule 4, Food safety measures and other standard), audit timer per process / area/ department, and details of auditor. Any change in duration of audit it will be inform to the FSSAI and permission for any change is taken before the commencement of the audit.

2.0 Audit Team requirement –

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a. Familiarity with the applicable legal regulations, certification procedures and certification requirements;
b. Thorough knowledge of the relevant assessment method and assessment documents;
c. Appropriate technical knowledge of the specific activities for which certification is sought and, where relevant, with associated procedures and their potential for failure (Technical experts who are not auditors may fulfil this function);
d. Understanding sufficient to make a reliable assessment of the competence of the organization to provide products, processes or services in its certified scope;
e. Ability to communicate effectively, both in writing and orally, in the required languages;
f. Free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example: providing of consulting services, training etc. to the organization; As per agreement with the audit team members it is mandatory to inform its auditing agency, prior to the assessment, about any perceived conflict of interest.

3. Intake form (Annexure 2 of Auditor manual for auditors FSSAI 2018) –
At the time of starting of audit this form will be filled by inspector on AMS portal, once the form is filled it cannot be change**.**

4. Confidentiality Agreement (Annexure 4 of Auditor manual for auditors FSSAI 2018)-
At the time of starting of audit this form will be filled by Inspector before the Commencing of every audit**.**

5. Auditing:

5.1 Opening and closing meeting: opening and closing meeting is done at the start and end of the audit and timing for opening and closing also noted.
The purpose of the opening meeting is to:

i. confirm the agreement of all parties (e.g. auditee, audit team) to the audit plan;
ii. introduce the audit team;
iii. ensure that all planned audit activities can be performed.

The meeting shall be chaired by the Auditor /Audit team leader, and the following items should be considered, as appropriate:

i. introduction of the participants, including an outline of their roles;
ii. confirmation of the scope of assessment;
iii. confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the Licensee;
iv. confirmation that the resources and facilities needed by the audit team are available;
v. confirmation of matters relating to confidentiality;
vi. the method of reporting, including any grading of audit findings, inspection checklists etc;
vii. methods and procedures to be used to conduct the audit based on sampling;
viii. confirmation that, during the audit, the Licensee will be kept informed of audit progress and any concerns;
ix. opportunity for the FBO to ask questions

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5.2 Conducting the audit activities

The following document/photographs should be uploaded by auditors while submitting the audit report-

1. Picture of updated FSSAI license displayed at a prominent location of the premise.
2. Picture of the internal structure and fittings of the premise depicting that they are made of non-toxic and impermeable material.
3. Picture showing availability of personnel hygiene facilities. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).
4. Document regarding potable water testing report from NABL accredited lab (meeting standards of IS: 10500), tested for quality semi-annually.
5. Document displaying availability of pest control program & pest control activities being carried out by trained and experienced personnel.
6. Document regarding annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine.
7. Picture of food handlers maintaining personal cleanliness (clean clothes, trimmed nails & water proof bandage etc).
8. Document of food handlers showing that they possess the necessary knowledge and skills and are trained to handle food safely.
9. Documents regarding retention of appropriate records and documents for a period of one year or the shelf- life of the product, whichever is more.
10. Documents/pictures displaying requisite time and temperature is being achieved, maintained, monitored & recorded while manufacturing/processing.
11. Picture showing packaging materials being used are of food grade and of sound condition. (Specific to Milk and milk product processing)
12. Picture showing cutlery, crockery used for serving and dinner accompaniments at dining service are clean, sanitized and free from unhygienic matter. (Specific to Catering)

5.3 The audit criteria

The audit team shall conduct an onsite audit as per the requirement and audit criteria. During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes, shall be verified and recorded. The audit criteria shall include the followings:

- Availability of valid FSSAI license
- Compliance of Schedule 4 of FSS Regulations
- Review any changes to activities conducted at the licensed food businesses that may affectthe businesses food safety risk
- Review changes to approved activities or processes
- Review of previous audit report and pending actions if any including non conformities not addressed
- Review of enforcement action taken by the Food Authority
- Previously issued Non conformities reviewed and discussed (Non conformities not addressed will be escalated)
- Licensed food businesses must produce evidence of corrective actions taken for all non conformities issued
- Review of food safety plan to ensure currency and accuracy including:
  - ♣ hazard analysis and control points (as determined by legislation),
  - ♣ finished product specifications,

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- ♣ monitoring records, flow charts,
- ♣ product testing results, and verification records.

- Inspection of the licensed food business and observation of processing and manufacturing practices
- Establish Non conformities to be issued and severity
- Issue of corrective action requests
- Complete audit report and notes

5.4 Closing meeting –

The Agenda for closing meeting may include the followings:

i. advising the FBO that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty;
ii. The method and timeframe of reporting, including any grading of audit findings;
iii. The procedure for closure of nonconformities including any consequences relating to the status of the FBO's license;
iv. The timeframe for the FBO to present a plan for correction and corrective action for any nonconformities identified during the audit;
v. Ensure all information recorded on report
vi. Ensure FBO is fully aware of what information will be communicated back to the Food Authority
vii. Ensure receiving of acknowledgement of the Nonconformities if any.
viii. Information about the complaint handling processes.
ix. Give opportunity for questions to the FBO.
x. Discuss and resolve any diverging opinions regarding the audit findings or conclusions between the audit team and the FBO (if applicable and where possible).

5.5. Where the deficiencies or non-conformances are detected, they are documented clearly and concisely and point out the regulatory requirements that are being contravened.

6. Audit reporting:

a) **Closure of Major Non Conformities**:

The auditor shall report any Major Non-Conformities (as defined in section 7.3.5(I) of this manual) to the Central or State Licensing Authority within twenty-four hrs through mail/ phone/ web portal etc. The auditor should ascertain that the information reaches the concerned CLA/SLA and FSSAI (Director (RCD)/ Director (FSMS)). The Central or State Licensing Authority after ascertaining the seriousness of the situation shall take regulatory action against the concerned food business operator. Once the information and other details have been shared by the auditor with concerned CLA/SLA, the next steps will be taken by CLA/SLA and the role of auditor ceases.

(b) **Closure of Minor Non Conformities**: In the case of Minor Non-Conformity (as defined in section 7.3.5(II) of this manual), the auditor shall set up an appropriate timeframe of not more than 15 days for its rectification and follow up, so that the non-conformance could be rectified. The complete audit report after rectification of non conformities will be uploaded by the agency on the FSSAI audit management portal. Failure by food business operator to rectify the minor non conformity within the specified timeframe shall be referred to the Central or State Licensing Authorities, as the case may be.

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7.0 Auditor **feed Back**: Auditor feed-back is taken regarding the Support received from PCPL regarding application review,
communication of audit plan
Information receives prior to audit
Appearance and Attitude of Inspector/Auditor
Inspector/Auditor s Ability to understand the issue
Technical Knowledge of Inspector/Auditor
Commercial Skills of Inspector/Auditor
Team Player of Inspector/Auditor
Conversant With Standard with Inspector/Auditor
How would you rate our web site regards the useful information
Would you suggest our IB.

8.0 Review of audit report: audit report and checked after the completion of audit and final approval done.

9.0 Inspection/audit report: The inspection/audit report will have following:

a) Identification of the issuing body: PCPL
b) Date(s) of inspection:
c) Unique identification and date of issue.
d) Name of FBO, with license number, address
e) Signature of inspector/auditor
f) statement of conformity where applicable; Non conformity forms,
g) the inspection results: Marks obtained and grades

Grading divided into 4 levels, i.e. Grade Status

i. **A+** Compliance exemplar at more than 90%
ii. **A** Compliance satisfactory 80 to 89%
iii. **B** need improvement 50 to 79%
iv. **No grade** non compliance below 50%

Audit check list and grading system as per Annex 5 of Auditor manual for Auditors FSSAI 2018

10. Inspection Certificate: no certificate is issued by PCPL. Only audit report along with non conformities is issued. Client is also informed the time duration to close all non conformities. Based on marks obtained the client is provided information on duration by which next audit will be due.

11. Failure by food business operator to rectify the minor non-conformity within the specified timeframe will be referred to FSSAI.

12.0 **Audit record**:
The PCPL maintain record system to demonstrate the effective fulfilment of the Inspection procedures and to enable an evaluation of the Audit.

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Reference:

Inspection time (Table-1for IAF code -03)

Food Handlers (Parameter-1)	No. Of production lines/ product group /no. of HACCP studies (Parameter-2)	Onsite man-day's (select parameter which ever is higher)
0-50	1	0.5
51-100	1-2	1.0
101-300	4	1.5
103-600	6	2.0
601-1000	8	2.5
>1000	10+	3.0

Note: For calculating the number of man-days, the parameter with the higher number of man days shall be taken into consideration. For eg: If the number of food handlers is 80 (i.e<100) and the number of production lines is 4 then the number of man-days will be 1.5 man-days (i.e. maximum of 1 and 1.5 man-days).

Inspection time (Table-2 For IAF code-30)

Food Handlers	On-site Man-days
0-25	0.5
26-50	1.0
50-100	1.5
101-1000	2.0

Reference-

Application and application review PC-F-01
Contract agreement for certification with client PC-F-02
Intake form for auditor PC-F-03
Quotation form PC-F-04
Declaration of conflict of interest (Form C) PC-F-05
Confidentiality agreement with auditor (Annexure 4) PC-F-06
Inspection plan PC-F-07
opening closing PC-F-08
FSSAI Inspection general manufacturing Check list PC-F-09
FSSAI Inspection milk and milk products PC-F-10
FSSAI Inspection catering PC-F-11
AUDIT DISCREPANCY/ NC form PC-F-13

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feedback form PC-F-14
Audit Report Review Form PC-F-41

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