

PrimusLabs Facility Audit Paperwork Checklist

v11.04 Audits

May-11

Please have the following paperwork available for the audit. The following list is a guide only and represents the minimum requirements for PrimusLabs audits. The auditor will potentially look at paperwork over the last year and/or since the last PrimusLabs audit. The list below is roughly in the order that the auditor will address the different sections of the audit.

An organization chart and process flow diagrams are useful documents for the auditor to see at the start of any audit at medium to large facilities.

Paperwork Listing	Storage & Distribution Center	Cooler and Cold Storage without HACCP	Cooler and Cold Storage with HACCP	Packing-house without HACCP	Packing-house with HACCP	Processing without HACCP	Processing with HACCP
FDA Food Security Registration documentation	Y	Y	Y	Y	Y	Y	Y
Regulatory inspection procedures	Y	Y	Y	Y	Y	Y	Y
Glass policy - statement, breakage procedure and glass register (if relevant)	Y	Y	Y	Y	Y	Y	Y
Written Standard Operating Procedures (SOP's) for food safety systems	Y	Y	Y	Y	Y	Y	Y
An index of the food safety SOP's	Y	Y	Y	Y	Y	Y	Y
Certification of inspection - backflow prevention system	N	Y	Y	Y	Y	Y	Y
Traceback and recall programs	Y	Y	Y	Y	Y	Y	Y
Mock recall paperwork (summary and supporting paperwork that shows traceability exercise logic)	Y	Y	Y	Y	Y	Y	Y
"On hold" and "rejected" product handling procedures	Y	Y	Y	Y	Y	Y	Y
List of approved commodity, ingredient and packaging item suppliers	Y if buying goods	Y if buying goods	Y if buying goods	Y	Y	Y	Y
Incoming goods letters of guarantee, third party audit reports/certifications and/or supplier certifications	Y if buying goods	Y if buying goods	Y if buying goods	Y	Y	Y	Y
MSDS book (inc. index)	Y	Y	Y	Y	Y	Y	Y
Specimen labels	Y	Y	Y	Y	Y	Y	Y
Chemicals inventories and/or usage logs	Y	Y	Y	Y	Y	Y	Y
SOPs for the changing and testing of water and ice systems (where applicable)	N	Y ⁴	Y ⁴	Y ⁴	Y ⁴	Y ⁴	Y ⁴
Pest control contract(s)	Y	Y	Y	Y	Y	Y	Y

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Pest control license(s)	Y	Y	Y	Y	Y	Y	Y
Pest control insurance(s)	Y	Y	Y	Y	Y	Y	Y
Pest control trap map(s)	Y	Y	Y	Y	Y	Y	Y
Pest control service (visit) records (inc. chemical application details and corrective actions)	Y	Y	Y	Y	Y	Y	Y
Buyer rejections/complaints and corrective actions	Y if selling goods	Y if selling goods	Y if selling goods	Y	Y	Y	Y
Consumer complaints and corrective actions	Y if selling goods	Y if selling goods	Y if selling goods	Y	Y	Y	Y
Records and corrective actions for Federal & State visits, 3rd party and 2nd party audits	Y	Y	Y	Y	Y	Y	Y
Processing records e.g. water temperatures, metal detection, pH, etc.	Y	Y	Y	Y	Y	Y	Y
Records and corrective actions of anti-microbial (free chlorine, ORP, ozone etc.) strength testing at start up and throughout the process	N	Y ⁵	Y ⁵	Y ⁵	Y ⁵	Y ⁵	Y ⁵
Hand/foot/tool dip logs or stock check/replenishment records for gel and spray stations	N	N	N	Y ¹	Y ¹	Y	Y
Records of tool accountability for knives and similar hand tools (inspection of cutting surfaces, quantities in/out on each shift)	N	Y ⁴	Y ⁴	Y ⁴	Y ⁴	Y ⁴	Y ⁴
Daily start up inspection logs	Y	Y	Y	Y	Y	Y	Y
Internal GMP self inspection records	Y	Y	Y	Y	Y	Y	Y
Internal food safety paperwork self inspection records	Y	Y	Y	Y	Y	Y	Y
Equipment calibration records	Y	Y	Y	Y	Y	Y	Y
Incoming goods (raw materials, ingredients and packaging) inspection records	Y if buying goods	Y if buying goods	Y if buying goods	Y	Y	Y	Y
Incoming truck temperature records	Y	Y	Y	Y	Y	Y	Y
Incoming truck sanitation check records	Y	Y	Y	Y	Y	Y	Y
An incident log and/or unusual occurrence corrective action (NUOCA) log	N	N	N	Y	Y	Y	Y
Finished good temperature checks	N	N	N	N	N	Y	Y
Preventative maintenance schedules	Y	Y	Y	Y	Y	Y	Y

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Preventative maintenance completion records	Y	Y	Y	Y	Y	Y	Y
Maintenance work logs	Y	Y	Y	Y	Y	Y	Y
Post maintenance sanitation records/procedures	N	N	N	Y	Y	Y	Y
Cleaning schedules (master sanitation)	Y	Y	Y	Y	Y	Y	Y
Cleaning procedures	Y	Y	Y	Y	Y	Y	Y
Records of cleaning operations (sanitation logs)	Y	Y	Y	Y	Y	Y	Y
Documented procedures and completion records for clean-in-place (CIP) activities	N	Y	Y	Y	Y	Y	Y
Records of drain cleaning operations	Y	Y	Y	Y	Y	Y	Y
Records of cooling unit servicing	Y	Y	Y	Y	Y	Y	Y
Records of cooling unit cleaning	Y	Y	Y	Y	Y	Y	Y
Written program and procedures for ATP testing	N	N	N	N	N	Y	Y
Food safety committee listing	N	N	N	Y	Y	Y	Y
Records of food safety meetings	N	N	N	Y	Y	Y	Y
Records of new hire food safety training, employee signed to company food safety policy	Y	Y	Y	Y	Y	Y	Y
Records of existing ongoing employee food safety training	Y	Y	Y	Y	Y	Y	Y
Written procedure requiring employees to report cuts/grazes and illness	Y	Y	Y	Y	Y	Y	Y
Records of training for sanitation employees	Y	Y	Y	Y	Y	Y	Y
Visitor and contractor food safety compliance logs	Y	Y	Y	Y	Y	Y	Y
Employee disciplinary procedures	Y	Y	Y	Y	Y	Y	Y
Equipment microbiological testing records	N	Y ²	Y ²	Y ²	Y ²	Y	Y
Equipment microbiological testing corrective action records where necessary	N	Y ²	Y ²	Y ²	Y ²	Y	Y
Environmental microbiological testing records	Y ³	Y ³	Y ³	Y ³	Y ³	Y	Y
Facility microbiological testing corrective action records where necessary	Y ³	Y ³	Y ³	Y ³	Y ³	Y	Y
Water microbiological testing records (on site sample)	Y	Y	Y	Y	Y	Y	Y

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Water microbiological corrective action records where necessary	Y	Y	Y	Y	Y	Y	Y
Ice microbiological test result records	N	Y	Y	Y	Y	Y	Y
Ice microbiological corrective action records where necessary	N	Y	Y	Y	Y	Y	Y
Packing/processing room temperature logs (if refrigerated)	N	N	N	Y	Y	Y	Y
Storage room temperature logs (probe(s) independent of thermostat)	Y	Y	Y	Y	Y	Y	Y
Shipping truck temperature logs	Y	Y	Y	Y	Y	Y	Y
Shipping truck sanitation logs	Y	Y	Y	Y	Y	Y	Y
HACCP training records and certificates	N	N	Y	N	Y	N	Y
Product descriptions	N	N	Y	N	Y	N	Y
Process flow charts	N	N	Y	N	Y	N	Y
Hazard analysis (charts and/or narratives) and CCP decisions	N	N	Y	N	Y	N	Y
HACCP chart showing CCPs, testing, frequencies, corrective actions, verification plans	N	N	Y	N	Y	N	Y
CCP monitoring records	N	N	Y	N	Y	N	Y
CCP validation documentation	N	N	Y	N	Y	N	Y
CCP deviation, non compliance records	N	N	Y	N	Y	N	Y
CCP verification documentation	N	N	Y	N	Y	N	Y
Evidence of HACCP discussions at the management level	N	N	Y	N	Y	N	Y
Records of HACCP system reviews	N	N	Y	N	Y	N	Y
HACCP self audit records	N	N	Y	N	Y	N	Y
Written SOPs for the CCP monitoring processes	N	N	Y	N	Y	N	Y
Evidence of HACCP discussions at the management level	N	N	Y	N	Y	N	Y
Independent audits of HACCP program	N	N	Y	N	Y	N	Y
Visitor and contractor signing in and out logs	Y	Y	Y	Y	Y	Y	Y

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Inbound and outbound truck seal number records	Y	Y	Y	Y	Y	Y	Y
Food security policies (manuals))	Y	Y	Y	Y	Y	Y	Y
List of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies	Y	Y	Y	Y	Y	Y	Y
Food security training records	Y	Y	Y	Y	Y	Y	Y
Log showing who has access to sensitive areas e.g. chemical stores	Y	Y	Y	Y	Y	Y	Y
Documented system for protecting the security of food safety documentation and computer systems	Y	Y	Y	Y	Y	Y	Y
Chemicals inventories and/or usage logs	Y	Y	Y	Y	Y	Y	Y
Documented allergen plan (if allergens used on site)	Y	Y	Y	Y	Y	Y	Y
Allergen sanitation procedures and records (if allergens are used on site)	Y	Y	Y	Y	Y	Y	Y
Allergen training records (if allergens are used on site)	Y	Y	Y	Y	Y	Y	Y
Records supporting the country of origin labeling e.g. bill of lading, production records, etc.	N	N	N	Y	Y	Y	Y
Is the on-site laboratory (where applicable) completely enclosed and separated from production and/or storage areas?	N	N	N	N	N	Y	Y
Do laboratory test results indicate test procedures meet accepted standards?	Y	Y	Y	Y	Y	Y	Y
Is there an organizational chart showing who has food safety responsibilities and to whom they report?	Y	Y	Y	Y	Y	Y	Y
Is there a documented food safety plan?	Y	Y	Y	Y	Y	Y	Y
Is there a documented food safety policy?	Y	Y	Y	Y	Y	Y	Y
Are there written specifications for purchased goods (raw materials, ingredients and packing materials)?	Y if buying goods	Y if buying goods	Y if buying goods	Y	Y	Y	Y
Are there written specifications for finished goods?	N	N	N	Y	Y	Y	Y

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Is there a written procedure for approval and continued monitoring of suppliers of raw materials, ingredients, finished goods and packaging materials?	Y if buying goods	Y if buying goods	Y if buying goods	Y	Y	Y	Y
Is there a written document control procedure describing how documents will be maintained, updated and replaced?	Y	Y	Y	Y	Y	Y	Y
Does finished product coding clearly link to supplier(s) of incoming materials? (Auditor performs a live traceback test to verify the 2.2.1 documentation).	Y	Y	Y	Y	Y	Y	Y
Does the facility have documented evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled?	N	Y	Y	Y	Y	Y	Y
Have operating limits and frequencies been determined for the CCPs?	N	N	Y	N	Y	N	Y
Notes							
<p>1) Hand Dip Logs are required for packing houses that have products that are washed or unwashed, but are viewed as ready-to-eat. This includes berries, peppers, citrus, apples, stone fruit, etc. Exempt products are those that need cooking or outer layer e.g. rind, peel, skin is not eaten or used as an integral part of the product i.e. as a food item.</p> <p>2) Equipment microbiological testing records are required in packing houses that wash the produce in some form except for produce that has to be cooked prior to consumption or outer layer e.g. rind, peel, skin is not eaten or used as an integral part of the product i.e. as a food item. Coolers that use ice and/HVACS are also expected to have these records.</p> <p>3) Enviromental microbiological testing records are required in packing houses that wash the produce in some form except for produce that has to be cooked prior to consumption or outer layer e.g. rind, peel, skin is not eaten or used as an integral part of the product i.e. as a food item. Coolers and storage units that store wet product and/or store product at higher humidities are expected to have these records.</p> <p>4) SOP for water changing product is being washed. SOP for anti-microbial testing of the water is required where the water is being recycled and an anti-microbial is being used.</p> <p>5) Records of anti-microbial testing of the water is required where the water is being recycled and anti-microbial is being used.</p>							