PRIMUSLABS.COM FACILITY QUALITY ASSURANCE SYSTEMS AUDIT MODULE v06.01

SECTION 1: QUALITY ASSURANCE FACILITY TOUR

Category	#	Question	Total Points	Compliance Criteria	Auditor Instruction
General Food Quality	1.1.1	Is there is a designated person responsible for the operations quality assurance programs?	5	There should be a person who is designated to manage and co-ordinate the operation's quality assurance programs. This person should be given adequate authority to perform their tasks, manage subordinates and facilitate both with other departments and also the direct customers.	
General Food Quality	1.1.2	Are adequate resources allocated to the operations quality assurance programs?	10	There should be adequate resources available to perform all the various quality assurance tasks. The resources should be such that they cover all the production times including swing shifts, night shifts and weekend work. Adequate provisions should be placed to cover absences including vacations, colleague training, sickness leave, etc.	
Facility Tour Raw Materials	1.2.1	Are raw material quality attribute checks being performed correctly (commodities, ingredients, food contact and non-food contact packaging)?	10	Raw material quality attribute checks should be carried out properly and as per any stated SOP's (where they exist). Quality attributes might include size grading, visible surface blemishes, color, shape, smell, pH, sugar content, etc. Packaging should be checked for print quality, color and any integrity issues (where relevant). Each incoming lot should be checked - sample size will depend on the type of item being checked.	The auditor should observe the Raw Material QA Employee carrying out these tasks.
Facility Tour Raw Materials	1.2.2	Are raw material temperature checks being performed correctly for raw materials (commodities and ingredients) that are temperature sensitive with respect to quality attributes?	10	For raw materials that are temperature sensitive there should be a temperature check of each material on arrival using a calibrated temperature probe against any stated SOP instructions (where they exist).	The auditor should observe the Raw Material QA Employee carrying out these tasks.
Facility Tour Raw Materials	1.2.3	Are raw materials (commodities and ingredients) stored at the correct temperatures that ensure that quality is maintained as far as possible?	10	For raw material commodities and ingredients that are temperature sensitive there should be adequate provision of temperature controlled storage. In some cases there might also be a need for humidity control.	The auditor should ensure that the materials are being stored in the correct conditions (temperature and where relevant humidity).

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Facility Tour Raw Materials	1.2.4	Are raw materials (commodities, ingredients, food contact and non-food contact packaging) properly marked with rotation codes e.g. receipt dates, manufacture dates?	5	For quality purposes raw materials should be coded with some form of date rotation coding in order to ensure both good stock rotation and help prevent materials going past their "optimum" quality window. Employing expiry coding is ideal since this helps maintain the quality of the finished product. Coding should at least be pallet specific, but sometimes might be container specific for less than full pallet purchases.	
Facility Tour Raw Materials	1.2.5	Are raw materials (commodities, ingredients, food contact and non food contact packaging) used on a FIFO basis and within any stated expiry coding?	5	For quality purposes raw material commodities and ingredients should be rotated using the identified coding. Some materials are rotated based on quality attributes e.g. tomatoes, which are rotated on color.	
Facility Tour Raw Materials	1.2.6	Are raw materials (commodities, ingredients, food contact and non-food contact packaging) that do not meet the specified quality requirements visibly separated and clearly identified as being "on hold" and/or rejected or downgraded in some manner?	10	Raw material commodities, ingredients and packaging that for some reason are not meeting the required quality (or any other issue) attributes should be clearly marked up as "on-hold" and/or "rejected". Reason and date should be identified on tags. These items should not be commingled with items that are acceptable (where possible physically separated, with designated areas).	
Facility Tour Raw Materials	1.2.7	For raw material items (commodities and ingredients) that have optimum storage temperature for quality reasons, are there raised shipping docks with sealed door buffers in order to maintain the optimum storage temperature?	5	For raw materials that are temperature sensitive, operations should be fitted with raised docks and door buffers which help maintain the cold chain.	
Facility Tour Operations	1.3.1	In manual quality selection processes, are the employees selecting correctly?	15	Employees working on product selection lines should be seen to be proficient at the task they are carrying out i.e. removing either the good (positive selection) or the bad (negative selection).	Auditors should observe the selection processes.
Facility Tour Operations	1.3.2	In manual quality selection processes, are the selection belts and equipment designed adequately e.g. with easy reach for selectors and operating properly (the belt speed is not too fast, etc.)?	5	Manual selection belts and other systems should be designed to help ensure that the quality grading process occurs properly. This might include considerations like the belt height, belt width, the speed of the belt (relative to the amount of product on the belt) and how the product is presented e.g. is the product conveyed on spinning rollers.	
Facility Tour Operations	1.3.3	In manual quality selection processes, is the lighting above the selection areas adequate for the selection duties being performed?	5	There should be adequate lighting provided for any quality grading process. This is not only a factor of the strength of the lighting, but also the type of the light e.g. the color (hue, color temperature, color rendering index, etc.) of the lighting. Ideally the artificial lighting hue should give the product its natural daylight color appearance as far as possible.	Auditors are not expected to carry light meters to check this issue, but must make a common sense decision on the type and strength of lighting available. As a very rough guide @500 Lux (46 foot candles), at point of use, in this case the selection surface. The lighting hue ideally would be as close to daylight as possible, the product should look like its natural color when being graded.

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Facility Tour Operations	1.3.4	In manual quality selection processes, are trained employees rotated on a set basis or given adequate break times, so as to ensure that selection efficiency and standards are maintained?	5	Selectors should be either rotated between different jobs or given breaks so as to try and ensure that their grading standards are maintained. Factors like the types of product, types of quality issues, amount of product grading, mode of selection, etc., will affect the graders ability to maintain their grading efficiency.	Auditors should enquire about staff rotations and break times.
Facility Tour Operations	1.3.5	With automated quality selection processes, (e.g. color sorters) is the equipment operating properly, i.e. have the right set points, rejection systems working correctly, calibrated correctly?	15	Automated selection systems (e.g. color sorters, sizers, item weight graders) should be set up properly e.g. on a weight grader the weight intervals should be inputted correctly on the computer. If the system has rejection mechanisms, these should be working properly. The machine should be calibrated.	Auditors should observe the machinery in operation and especially the "output". If possible the auditor should try and observe the machinery calibration processes.
Facility Tour Operations	1.3.6	Are check weighing or counting systems working correctly and calibrated e.g. are the set points correct, allowing for tares, rejecting setting working properly, etc.? *This includes both "in line" equipment, as well as stand alone equipment.*	10	Check weighing and/or counting systems should be working properly, have the correct set points including tares for moisture loss and packaging. The rejection systems should be operating properly. The check weight systems might be "in line" (automated) or a manual system that is set by the side of the line.	
Facility Tour Operations	1.3.7	Are quality related process control steps being monitored correctly (e.g. citrus degreening)? This question excludes selection processes which are covered in the questions above.	10	Process control steps which enhance the product quality should be monitored e.g. degreening citrus fruit (temperature, humidity and ethylene). Some quality processes may actually might be food safety issues if not controlled properly, e.g. use of scurf suppressant fungicides on potatoes are for visual quality, but if not applied correctly might be a legal and/or food safety issue.	
Facility Tour Operations	1.3.8	Where relevant (e.g. mixed fresh-cut produce items), are product components being measured and mixed correctly relative to a specified formulation?	5	Where a finished product is made of multiple commodities or ingredients, the various materials should have been prepared, weighed and mixed properly. Often this is governed by a recipe system.	
Facility Tour Operations	1.3.9	Are packaging machines and manual packaging operation occurring correctly e.g. neat seals, legible printing, neat label applications?	5	Packaging is a party of the products quality profile. The neatness of the seals, the legibility of any printed materials, label application neatness and consistency between products should be accounted for. Packaging formats include, bags, clamshells, over wraps and also the outers (e.g. cartons), should also be packed properly and consistently.	
Facility Tour Operations	1.3.10	At the production line, are products that are downgraded or rejected (culled) in the production process, clearly segregated from the products that meet the required quality standards?	5	In the production areas, products that are downgraded or culled should be clearly separated from materials that meet the specified standards. For example, this might be completed by using a cull belt, cull buckets or bins, etc.	

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Facility Tour Operations	1.3.11	Where relevant, if any "rework" material is being handled, are the selection, packaging and checkweighing processes operating correctly?	5	Where rework does or might occur, the materials should be checked for their condition in order to ensure that they have not been degraded by the production process. Sometimes rework is specifically perfomed for quality reasons, e.g. re-selecting late season stored apples. Rework might need re-labeling and might need reweighing.	
Facility Tour Operations	1.3.12	Where relevant, if any "work in progress" is created, is this material being marked with rotation codes and any quality parameter limits, e.g. size grading in the case of pre-sized product?	5	"Work in progress" (WIP) materials should be clearly labeled not only for safety reasons but also for quality purposes. Production days and/or expiry days, help ensure that quality is maintained. Quality attribute characteristics e.g. size grading, ensure that the WIP is properly identified.	
Facility Tour Finished Products	1.4.1	Are finished product quality attribute checks e.g. color, size, condition, etc., being performed correctly on the actual food item (as opposed to packaging) and corrective actions employed where necessary?	15	Finished products quality attribute checks should be carried out properly and as per any stated SOP's where they exist. Quality attributes might include size grading, visible surface blemishes, color, shape, smell, pH, sugar content, etc. Each outgoing lot should be checked - sample size will depend on the type of item being checked.	The auditor should observe the finished products QA employee carrying out these tasks.
Facility Tour Finished Products	1.4.2	Specifically are finished product packaging checks including labeling and print quality, being performed correctly e.g. print quality, seal neatness, label positioning, cap fitting, etc.?	5	Finished products packaging quality attribute checks should be carried out properly and as per any stated SOP's where they exist. Quality attributes might include seal integrity, print quality, label application neatness, etc. Each outgoing lot should be checked - sample size will depend on the type of item being checked.	The auditor should observe the finished products QA employee carrying out these tasks.
Facility Tour Finished Products	1.4.3	Where applicable, are legally required quality statements (markings) being displayed properly on the outers (e.g. cartons) and unit packs (e.g. clam shells)? For example USDA quality grading, size grading etc. Where relevant nutritional claims should also be properly displayed?	5	Some items are legally required to show quality statements. Sometimes this is a grade e.g. U.S.D.A #1. Sometimes size grading markings are required on the size of a product. In some countries, the % amount of a component has to be displayed in the ingredients, (called "Quantitative Ingredient Declarations"). Requirements for nutritional declarations vary from country to country.	Auditors should check the labeling of the products being produced and also be aware of the national and local legislation.
Facility Tour Finished Products	1.4.4	Are finished product temperature checks being performed for products that are temperature sensitive with respect to quality attributes?	10	For finished products that are temperature sensitive there should be a temperature check of each lot of finished product using a calibrated temperature probe against any stated SOP instructions, where they exist.	The auditor should observe the finished goods QA employee carrying out these tasks.
Facility Tour Finished Products	1.4.5	Are finished product weight checks and/or count checks being performed correctly, e.g. at the required frequency, right sample size ?	10	Finished products weight and/or count checks should be carried out properly and as per any stated SOP's where they exist. Each outgoing lot should be checked - sample size will depend on the type of item being checked.	The auditor should observe the finished goods QA employee carrying out these tasks.
Facility Tour Finished Products	1.4.6	Are finished products stored at the correct temperatures, that ensure quality attributes are maintained as far as possible?	5	For finished products that are temperature sensitive there should adequate provisions for temperature controlled storage. In some cases there might also be a need for humidity control.	The auditor should ensure that the materials are being stored in the correct conditions (temperature and where relevant humidity).

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Facility Tour Finished Products	1.4.7	Are finished products (at the pallet level) properly marked with rotation codes, e .g. receipt dates, manufacture dates etc.?	5	For quality purposes finished goods should be coded with some form of rotation date coding in order to ensure both good stock rotation and prevent materials going past their "optimum" quality window. Employing expiry coding is ideal since this helps maintain the quality of the finished product. Pallet and carton coding is expected, but ideally for prepacked product, each individual unit should be coded.	
Facility Tour Finished Products	1.4.8	Are finished goods rotated while in stock, so that the first manufactured is the first to be shipped, unless market orders dictate otherwise?	5	For quality purposes finished product coding should be rotated using the identified coding.	
Facility Tour Finished Products	1.4.9	Are finished goods that do not meet the specified quality requirements visibly separated and clearly identified as being "on hold" and/or rejected or downgraded in some manner?	10	Finished product coding that for some reason is not meeting the required quality attributes should be clearly marked up as "on-hold" and/or "rejected". These items should not be commingled with items that are of acceptable quality.	
Facility Tour Finished Products	1.4.10	For products that have optimum storage temperature for quality reasons, are there raised shipping docks with sealed doors buffers in order to maintain the optimum storage temperature?	5	For finished products that are temperature sensitive operations should be fitted with raised docks and door buffers which help maintain the cold chain.	
Facility Tour Finished Products	1.4.11	If there are any shipping trailers on the dock, are they pre-cooled to a temperature which is optimum for the products that are being shipped?	5	Trailers should be pre-cooled prior to loading so that they do not remove heat energy from the already cold product, thereby reducing quality. Note air temperatures will reflect the outside the air temperature once the trailer doors are open.	Auditor can touch the insulation inside the trailer. Where available the auditor should use infra-red or surface probes. Note air temperatures will reflect the outside the air temperature once the trailer doors are opened. Auditors should only check thermostat settings, if it is safe to access the trailer chiller unit read out.
Facility Tour QA Dept.	1.5.1	Are quality assurance attribute measuring devices, e.g. penetrometers, refractometers etc., working properly (i.e. are they in calibration)?	5	Quality Assurance dept. and production line quality assurance testing equipment should be in calibration. For example, using a test solution on a refractometer.	The auditor should ask to see some of the equipment being calibrated to make sure that the equipment is in calibrated properly.
Facility Tour QA Dept.	1.5.2	For temperature sensitive products, where the quality of a product is affected by temperature, are the temperature probes used working properly (i.e. are they in calibration)?	5	QA Dept. and production line QA temperature testing equipment should be in calibration. Note that this question pertains to temperature quality issues as opposed to food safety. Calibration checks might be done using a reference thermometer or using ice/boiling water.	The auditor should ask to see some of the equipment being calibrated to make sure that the equipment is being calbrated properly.
Facility Tour QA Dept.	1.5.3	Are quality assurance dept. scales working properly and correctly calibrated?	5	QA Dept. and production line QA scales should be in calibration. This is usually achieved by using a test weight, on a daily basis. In depth scale calibrations are covered in section 2.	The auditor should ask to see some of the equipment being calibrated to make sure that the equipment is be calbrated properly.

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Facility Tour QA Dept.	1.5.4	Are the required shelf life (retain samples), being collected and studied? Frequency depends on finished product variability?	3	Shelf life samples should be collected. The frequency will vary from one type of product to another depending on expected quality variations. For example with some products, keeping daily shelf life might be necessary (e.g. juices), for other products weekly might be acceptable (e.g. mushrooms from a single farm).	Auditors should check the frequency policy before deciding whether the frequency is being met. Auditors should only question the frequency of shelf sampling if they feel that the auditee is operating at a very low frequency relative to the type of product and the quality variations.
Facility Tour QA Dept.	1.5.5	Is the product shelf life area operating in right conditions e.g. temperatures, lighting etc., and samples are clearly labeled with production and expiry date?	3	The shelf life area should try and mimic the expected distribution chain as much as possible. Samples should be retained for the expected shelf life of the product. Samples should be clearly labeled with production and expiry dates (this can be hand written on the products, if the products are not coded).	

SECTION 2: QUALITY ASSURANCE DOCUMENTATION

Category	#	Question	Total Points	Compliance Criteria and Recommendations	Auditor Instruction
General Food Quality Documentation	2.1.1	Are there records of management meetings that show that the Quality Assurance Programs, the results of the Quality Assurance Program and any other information (e.g. customer complaints) are discussed?	5	There should be records that show that quality assurance issues are being discussed at management level (notes should show who attended the meetings). Discussions could include quality attribute processes, records, customer complaints, new product developments, etc. Meetings should be occurring at least quarterly, ideally monthly. QA might be an agenda point on a larger meeting, e.g. monthly sales meetings.	Auditors should accept records that show briefly what was discussed and any actions planned. Auditors should not demand detailed minutes. Auditors should accept topic notes that are embedded within meeting notes for larger topics e.g. sales meetings notes.
General Food Quality Documentation	2.1.2	Are there records of internal quality assurance system audits?	5	Internal audit scopes should include quality assurance systems, ensuring that quality checks are occurring properly and records are being maintained properly (along with corrective actions). These audits should occur at least quarterly, but ideally monthly.	
General Food Quality Documentation	2.1.3	Is there a Quality Manual that includes Standard Operating Procedures (SOP's) for processes and testing related to quality attribute management of a product? Does the manual also include a register of master forms?	5	There should be a manual in existence that collates the SOP's that relate to quality attribute management e.g. check weighing SOP. The manual does not have to be dedicated to quality issues only. The manual should also include copies of the forms that are being used.	

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Documentation Raw Materials	2.2.1	Have adequate raw material specifications been created or provided for raw material food commodities and ingredients, which show quality attributes and tolerances?	10	There should be specifications for raw material commodities and ingredients that outline the quality requirements of the procured items. These specification should show tolerances where relevant.	
Documentation Raw Materials	2.2.2	Have adequate raw material specifications been created or provided for food packaging materials (including both food contact and non-food contact materials), which show quality attributes e.g. thickness, colors, etc.?	5	There should be specifications for food contact and non-food contact packaging that outline the quality requirements of the procured items. These specifications should show quality parameters that might include colors, gauge, perforation, oxygen transmission rates, cardboard grade, dimensions and any other relevant quality attributes. Packaging includes cartons, labels, as well as clamshells and bags.	
Documentation Raw Materials	2.2.3	Are there letters of guarantee or proof of third party audits regarding the quality assurance systems in operation at the raw material suppliers of commodities and ingredients?	10	There should be some form of letter of guarantee or third party audit certificates, that state that the supplier has quality systems in place devoted to ensuring that materials supplied meet any quality parameters. Third party certificates and letters of guarantee that only pertain to food safety are not acceptable, but certificates of analysis (COA's) that cover quality attributes are acceptable.	Auditors should remember that the supplier (vendor) assurance should pertain to quality as opposed to food safety.
Documentation Raw Materials	2.2.4	Are there letters of guarantee or proof of third party audits regarding the quality assurance systems in operation at the raw material suppliers of food packaging materials (including both food contact and non-food contact materials)?	5	There should be some form of letter of guarantee or third party audit certificates, that state that the supplier has quality systems in place devoted to ensuring that materials supplied meet any quality parameters. Third party certificates and letters of guarantee that only pertain to food safety are not acceptable, but certificates of analysis (COA's) that cover quality attributes are acceptable.	Auditors should remember that the supplier (vendor) assurance should pertain to quality as opposed to food safety.
Documentation Raw Materials	2.2.5	Are commodity and ingredient raw material quality attribute checks being recorded, e.g. visual condition, sugar testing, size grading, etc; at least one record per lot?	10	There should be records showing that incoming raw materials quality attributes are checked. There should be a record for each batch/lot of received materials. Where specifications exist, the raw material quality check should use the stated attributes, limits and tolerances. Certificates of analysis that include quality parameters are acceptable. Any out of specification issues should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.
Documentation Raw Materials	2.2.6	Are food packaging materials (including both food contact and non-food contact materials) quality attribute checks being recorded e.g. print quality; at least one record per lot?	5	There should be records showing that incoming packaging materials quality attributes are being checked. There should be a record for each batch/lot of received materials. Where specifications exist, the raw material quality check should use the stated attributes, limits and tolerances. Certificates of analysis that include quality parameters are acceptable. Any out of specification issues should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.

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Documentation Raw Materials	2.2.7	Are there records of incoming raw material commodity and ingredient temperature checks for raw materials that are temperature sensitive?	5	There should be records showing incoming raw material temperature testing results for materials that are temperature sensitive. There should be a record for each batch/lot of received materials. Where specifications exist, the raw material temperature check should use the stated limts and tolerances. Any out of specification issues should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.
Documentation Raw Materials	2.2.8	Are suppliers of raw materials informed in writing about quality issues (e.g. incoming QA issues, production issues, customer complaints, etc.), that are attributed to the materials that they are providing the auditee?	3	There should be records of communications showing that suppliers who have had materials that have caused quality problems (e.g. raw material QA in the production process, traced back from customer complaints or buyer rejections) have been informed. These records should also include any corrective actions that have been taken.	
Documentation Raw Materials	2.2.9	For commodities that are stored for an extended length of time, are there periodic recorded quality attribute checks?	5	For commodities that are stored for extended length of time (e.g. over 14 days) there should be recorded periodic quality checks. The frequency will vary depending on the type of product and also the experience within the organization about storing the material. For example, apples that are stored 2 to 12 months, then a monthly quality check would be expected.	Auditors should investigate the length of time the commodity is stored and the quality degradation issues involved. A monthly frequency should usually be viewed as a minimum frequency.
Documentation Raw Materials	2.2.10	Are there records of raw material storage room temperatures (recorded using a probe that is independent from the thermostat)?	5	There should be air temperature records for the rooms used for storing temperature sensitive raw materials. The temperature probes used to measure these air temperatures should be independent from the thermostat systems. Any out of specification issues should be linked to documented corrective actions.	
Documentation Operations	2.3.1	Are there documented quality training programs and training records for new employees who work as manual quality selectors on the production lines?	10	There should be documented quality training programs for new employees that state the key quality attributes of the product(s) being selected, any allowed tolerances and specific culling and downgrading requirements. There should be records showing that the new employees have completed this training to everyone's satisfaction. Ideally new employees will be checked to ensure that they have understood their training.	
Documentation Operations	2.3.2	Are there documented ongoing quality training programs and training records for existing employees who work as manual quality selectors on the production lines?	15	There should be documented ongoing quality training programs for existing employees that help ensure that selectors remember the key quality issues that they are selecting for and they are aware of the tolerances. There should be records showing that the employees have completed this training to everyone's satisfaction. It might be that the training program adapts based on the known issues, e.g. from incoming quality reports or from customer feedback.	

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Documentation Operations	2.3.3	Is there sufficient documented guidance showing the production line quality selectors, the required quality attributes for product and/or the tolerances for the quality issues they are selecting out?	5	There should be easy-to-read guidance documentation for the quality selectors that shows the key requirements, tolerances and known quality issues with the items they are being asked to select. This might take several forms e.g. specifications which are given to employees, wall signs that show the main issues, laminated cards carried by staff, etc.	
Documentation Operations	2.3.4	Are there records of automated quality selection processes calibration checks e.g. color sorters, size graders etc., which show frequency, results and corrective actions?	5	There should be records showing that the "in-line" sorting equipment e.g. color sorter, item size grader, have been calibrated properly. Frequency and methodology should at least be as per manufacturers recommendations. Any corrective actions should be recorded.	
Documentation Operations	2.3.5	Are quality related process control step(s) parameters being recorded properly? This question excludes selection processes which are covered in the questions above.	10	Process control steps which enhance the product quality should be monitored and parameters recorded e.g. degreening citrus fruit (temperature, humidity and ethylene). Other examples include ripening, e.g. bananas, use of coatings e.g. waxes. This question might over lap with food safety issues.	Some processes designed to improve the quality of an item might, if not performed properly, render a product illegal or unsafe, e.g. post-harvest fungicide used on potatoes.
Documentation Operations	2.3.6	Where relevant are product formulations for multi-component products being recorded properly for each production run, e.g. mixed fresh-cut produce items?	5	The mix of multi-component products affects the quality of the finished products. There should be batch records, showing formulations - these often follow a stated specification (formulation sheet, recipe etc.). This will be non-applicable for single components finished products.	
Documentation Operations	2.3.7	Are there records of production line check-weighing equipment calibrations checks which show frequency, results and corrective actions?	5	There should be records showing that the check-weighing equipment has been calibrated properly. There should be a daily in house cross reference check, e.g. use of a known check weight - this will check to see if the balance has been moved or knocked off balance in some way. There should be records of at least an annual full scale calibration check. Any corrective actions should be recorded.	
Documentation Operations	2.3.8	Where relevant, are rework quality attribute checks being recorded correctly, e.g. visual condition, sugar testing, size grading, etc.?	5	There should be records showing that rework quality attributes are checked. There should be a record for each batch/lot of materials. Where specifications exist, the "work in progress" quality check should use the stated attributes, limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Rework can take many forms, e.g. shredded lettuce packs that are opened and returned to an earlier process step in the production line; apples that have been stored for months, being resorted due to quality issues detected in storage. The auditee might use an existing quality attribute template and record that on this occasion it was a rework operation.
Documentation Operations	2.3.9	Where relevant, are "work in progress" a.k.a. partly-processed material quality attribute checks being recorded correctly e.g. pre-sized apples etc.?	5	In some processes raw materials are part-processed and then stored either for long or short periods of time prior to being used for the finished product production. Examples include pre-size graded apples, bulk chopped items stored ready for later retail packing. There should be records showing that "work in progress" quality attributes are checked. There should be a record for each batch/lot of materials. Where specifications exist, the "work in progress" quality check should use the stated attributes, limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.

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Documentation Operations	2.3.10	Where relevant, are "work in progress" a.k.a. partly-processed material temperature checks being recorded correctly for products whose quality attributes are temperature sensitive?	5	There should be records showing "work in progress" temperature testing results for materials that are temperature sensitive. There should be a record for each batch/lot of "work in progress" materials. Where specifications exist, the "work in progress " temperature check should use the stated parameters and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.
Documentation Operations	2.3.11	**Optional Question**. Are there recorded quality attribute and quantity checks of the downgraded and rejected materials?	0	Performing quality checks on culls and downgrades helps ensure that the "right" materials are downgraded. Also helps to give an overview of the main issues causing downgrades which might help the raw material procurement function.	If cull checks are performed, the auditor should expect to see records of this work.
Documentation Finished Products	2.4.1	Have adequate finished product specifications been created that clearly define product quality attribute requirements and tolerances?	10	There should be specifications for finished products that outline the quality requirements including packaging as well as the product itself. These specifications should show limits and tolerances.	
Documentation Finished Products	2.4.2	Are finished product quality attribute checks on the actual food item being recorded, e.g. visual condition, sugar testing, size grading, etc; at least one record per lot?	15	There should be records showing that actual food item quality attributes are being checked (this excludes taste testing and packaging checks, see below). For example in a bag of shredded lettuce, check on the lettuce itself. There should be a record for each batch/lot of finished products. Where specifications exist, the finished product check should use the stated attributes, limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.
Documentation Finished Products	2.4.3	Specifically, are finished product quality taste testing (organoleptic) checks being recorded as required - the type and frequency of testing is dictated by the type of product being produced?	10	Taste testing products should be carried out as a matter of routine. This should include smell as well as tasting. There should be records of taste testing. Frequency depends on the type of product and expected variability, e.g. field to field, batch to batch. Any out of specification issues, should be linked to documented corrective actions.	
Documentation Finished Products	2.4.4	Specifically, are finished product packaging checks including labeling and print quality, being recorded properly, e.g. print quality, seal neatness, label positioning, cap fitting, etc.?	10	There should be records showing packaging quality attributes are being checked. For example in a bag of shredded lettuce, check print quality and legibility, seal neatness and angle and any label application positioning. There should be a record for each batch/lot of finished products. Where specifications exist, the finished product check should use the stated attributes, limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.
Documentation Finished Products	2.4.5	Are finished product temperature checks being recorded for products that are temperature sensitive with respect to quality attributes? Should be checked per lot.	10	There should be records showing finished products temperature testing results for materials that are temperature sensitive. There should be a record for each batch/lot of received materials. Where specifications exist, the finished product temperature check should use the stated limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	Auditors should check for corrective action documentation when stated limits have been exceeded.

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Documentation Finished Products	2.4.6	Are finished product weight checks being recorded?	10	There should be records showing finished product check weights are being performed. Finished product weights should take into account packaging and moisture loss tares where applicable. There should be a record for each batch/lot of finished products. Where specifications exist, the finished product check should use the stated attributes, limits and tolerances. Any out of specification issues, should be linked to documented corrective actions.	
Documentation Finished Products	2.4.7	Are there records of the finished product storage room temperatures? Should be recorded using a probe that is independent from the thermostat.	5	There should be air temperature records for the rooms used for storing temperature sensitive finished products. The temperature probes used to measure these air temperatures should be independent from the thermostat systems. Any out of specification issues, should be linked to documented corrective actions.	
Documentation Finished Products	2.4.8	Are there records of shipping trailer temperature checks, indicating that the trailer was pre-cooled prior to loading? (For trailers that are used to ship temperature sensitive products).	5	For temperature sensitive products, trailers should be pre-cooled prior to loading, so that they do not remove heat energy from the already cold product, thereby reducing quality. There should be records of the shipping trailer temperature checks where temperature sensitive products are being shipped. Trucks are checked by testing insulation (as opposed to air temperatures).Temperature criteria should be documented. Checks are normally done per trailer. Any out of specification issues, should be linked to documented corrective actions.	Auditor should accept infra-red or surface probes or, insulation hand touch temperature records. Note air temperatures will reflect the outside air temperature once the trailer doors are open.
Documentation Finished Products	2.4.9	Are there records of buyer and/or consumer quality attribute related rejections and complaints, along with corrective actions? Where useful, were these issues trend analyzed?	5	Complaints and rejections emanating either from the direct buyers and/or the product consumers should be recorded. Records should include the date, time, product name, lot code, quantity and reason for the complaint/rejection. Where possible, corrective actions should be noted. If there are more than 100 incidents, then there should be some form of trend analysis occurring.	
Documentation QA Dept.	2.5.1	Are there training programs and records for new quality assurance dept. employees (or other new employees carrying out quality assurance functions) that orientates them in their jobs and ensures they are capable of carrying out their assigned duties?	10	There should be documented quality training programs for new quality assurance dept. employees with respect to their key roles in ensuring that the required product quality issues are maintained. There should be records showing that the employees have completed this training to everyone's satisfaction. Ideally new employees will be checked on to ensure that they have understood their training.	

Category	#	Question	Total Points	Compliance Criteria	Auditor Instruction
Documentation QA Dept.	2.5.2	Are there ongoing training programs and records of existing quality assurance dept. employee (or other employees carrying out quality assurance functions) training e.g. refresher training, system updates, etc.?	15	There should be documented ongoing quality training programs for existing quality assurance dept. employees which acts as refresher training, updates any system changes and the implementation of innovations. There should be records showing that the employees have completed this training to everyone's satisfaction. It might be that the training program adapts based on the known issues, e.g. from incoming quality reports or from customer feedback.	
Documentation QA Dept.	2.5.3	Are there records of calibration for quality attribute measuring equipment, e.g. penetrometers, refractometers, etc.?	10	There should be records showing that the quality attribute measuring equipment, e.g. penetrometers, refractometers have been calibrated properly. Frequency and methodology should at least be as per manufacturers recommendations. Any corrective actions should be recorded.	
Documentation QA Dept.	2.5.4	Are there records of calibration for temperature testing equipment where the operation is handling temperature sensitive items?	10	For temperature sensitive products, there should be records showing that temperature testing equipments has been calibrated properly. Frequency and methodology should at least be as per manufacturers recommendations. Any corrective actions should be recorded. Note that this question pertains to temperature quality issues as opposed to food safety. Calibration checks might be perfomed using a reference thermometer or using ice/boiling water.	
Documentation QA Dept.	2.5.5	Are there records of calibration for quality assurance dept. scales (as opposed to production scales) ?	5	There should be records showing that the quality assurance check weighing equipment has been calibrated properly. There should be a daily in-house cross reference check, e.g. use of a known check weight - this will check to see if the balance has been moved or knocked on balance in some way. There should be records of at least an annual full scale calibration check. Any corrective actions should be recorded.	
Documentation QA Dept.	2.5.6	Are there shelf life (retain sample) records for finished products, that show the product quality attributes at various points through to at least the end of the expected product shelf life?	3	There should be record showing product quality shelf life (retain sample) results. Records should be kept up until at least the expected end of product shelf life. Shelf life quality testing usually focuses on condition issues, e.g. decay. Please see specific questions below. The frequency of how often to perform shelf life testing and then the frequency of checking the product in the shelf life test will vary from product to product - short shelf life fragile products will need testing more frequently than hardy long shelf life products. Other factors include field, batch make up, etc.	
Documentation QA Dept.	2.5.7	Are there shelf life (retain sample) records for finished products, that show the taste (organoleptic) testing quality attributes at various points through to at least the end of the expected product shelf life or tested at the end of the expected shelf life only?	3	There should be records showing taste testing results of shelf life sampling. This should include smell as well as tasting. Taste testing might occur at different points through the shelf life or it might occur at the end of shelf life only. (See above question compliance criteria recording testing frequency).	

Category	#	Question	Total Points	Compliance Criteria	Auditor Instruction
Documentation QA Dept.	2.5.8	Are there shelf life (retain sample) records for finished products, that show the weight loss figure of the product over shelf life?	3	There should be records showing weight loss (moisture loss) results of shelf life sampling for products that are sold by weight to the buyer or customer and there is a chance of either buyer rejection or legal issues for the sale of underweights. Shelf life weight loss checking justifies applied moisture loss tares. Frequency depends on product type and packaging style. Bulk items can be on lower frequency basis than clamshells sold by weight.	