

## 21CFR110 versus 117

Revised: 10/22/15

| <b>GMP Category</b> | <b>GMP Topic</b>            | <b>110 Ref.</b> | <b>117 Ref.</b> | <b>110 Brief Description:</b>  | <b>117 Differences (if applicable)</b>                             |
|---------------------|-----------------------------|-----------------|-----------------|--|--|
| Personnel           | Disease                     | 10(a)           | 10(a)           | No illnesses or open sores/lesions that could contaminate equipment or product.  | Reference the Food Code; Some flexibility with covered lesions     |
|                     | Cleanliness                 | 10(b)           | 10(b)           | Maintain cleanliness when working in direct contact with food or food contact surfaces including:                                  | No Significant Changes   |
|                     | Outer Garments              | 10(b1)          | 10(b1)          | Wearing an outer garment that is clean   | Added protection from cross contact of food allergens              |
|                     | Personal Cleanliness        | 10(b2)          | 10(b2)          | Maintain adequate personal cleanliness   | No Significant Changes   |
|                     | Hand Washing                | 10(b3)          | 10(b3)          | Wash hands at appropriate times (before work, when soiled, after eating or using the bathroom)                                     | No Significant Changes   |
|                     | Jewelry                     | 10(b4)          | 10(b4)          | Remove jewelry or cover with a glove   | Added wording about "unsecured" jewelry                            |
|                     | Gloves                      | 10(b5)          | 10(b5)          | Maintain intact, clean and sanitary  | Removed recommendations about "impermeable material"               |
|                     | Hair nets, beard nets       | 10(b6)          | 10(b6)          | Wear in an effective way hair nets, beard nets, etc.   | No Significant Changes   |
|                     | Storing Clothing/Belongings | 10(b7)          | 10(b7)          | Store in designated areas away from food and food contact surfaces   | No Significant Changes   |
|                     | Eating, Drinking            | 10(b8)          | 10(b8)          | No eating or drinking except in designated areas away from food and food contact surfaces  | Drinking water is not allowed in areas where there is open product |
|                     | Food Contamination          | 10(b9)          | 10(b9)          | Protect against contamination of food, food contact surfaces or food contact packaging from microorganisms, foreign material, etc. | No Significant Changes   |
|                     | Education/Training          | 10(c)           | 10(c)           | Appropriate training for specific jobs based on need   | Now a requirement instead of a recommendation and moved to 117.4   |
|                     | Supervision                 | 10(d)           | 10(d)           | Appropriate and competent supervision will be assigned   | Moved to 117.4   |
| Plant and Grounds   | Grounds                     | 20(a)           | 20(a)           | Grounds shall be kept to protect against contamination including, but not limited to:  | No Significant Changes   |
|                     | External Storage            | 20(a1)          | 20(a1)          | Keep building perimeter free from pest harborage areas such as weeds, equipment, litter, etc.                                      | No Significant Changes   |
|                     | Roads and Yards             | 20(a2)          | 20(a2)          | Keep roads and yards maintained  | No Significant Changes   |
|                     | Drainage                    | 20(a3)          | 20(a3)          | Drainage areas will not permit seepage, foot borne filth or breeding areas for pests   | No Significant Changes   |

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|                     | Waste Treatment            | 20(a4) | 20(a4) | Waste treatment will not be a contamination source   | No Significant Changes  |
|                     | Grounds Outside Control    |        | 20(a5) |  | Added if grounds are bordered by grounds outside plants control and not maintained than additional pest control may be required |
|                     | Plant Construction/ Design | 20(b)  | 20(b)  | Suitable in size, construction and design for sanitary operation and include:  | No Significant Changes  |
|                     | Equipment Storage          | 20(b1) | 20(b1) | Sufficient space for equipment and storage   | No Significant Changes  |
|                     | Plant Construction         | 20(b2) | 20(b2) | Sufficient in space for separation of functions, ability to clean and maintain sanitary conditions   | Prevent against cross contamination and gave examples such as air flow systems and dust collection systems.                     |
|                     | Outdoor Vessels            | 20(b3) | 20(b3) | Outdoor vessels shall have protective covering, no harborage areas for pests, inspected, and skimming the fermentation vessels if applicable.  | Clarified wording about bulk vessels.   |
|                     | Floors, walls, ceilings    | 20(b4) | 20(b4) | Can be maintained, in good repair, space between, unobstructed, and cleanable  | No Significant Changes  |
|                     | Lighting                   | 20(b5) | 20(b5) | Adequate lighting so employees can do their job and equipment and storage can be maintained  | Revised wording to specify that good light is required in production, inspection areas and storage areas.                       |
|                     | Ventilation                | 20(b6) | 20(b6) | Minimize odors and vapors  | Added reference to cross contact and allergens  |
|                     | Screening                  | 20(b7) | 20(b7) | Provide when necessary to keep out pests   | No Significant Changes  |
| Sanitary Operations | General Maintenance        | 35(a)  | 35(a)  | Buildings, fixtures and other physical facilities shall be maintained in good repair and sanitary including utensils   | Minor wording changes - "clean" versus "sanitary"   |
|                     | Cleaning & Sanitizing      | 35(b1) | 35(b1) | Cleaning chemicals will be micro free and safe to use. Only toxic materials allowed in plant are ones required for: cleaning and sanitizing, laboratory testing, plant and equipment maintenance; and use in plant operations. | Cleaning and sanitizing compounds must be safe and effective and provide examples of ways to achieve compliance.                |
|                     | Toxic Cleaners             | 35(b2) | 35(b2) | Toxic compounds will be stored away from product and product contact surfaces.   | Removed recommendation to follow all relevant Federal, State and Local agencies rules.  |
|                     | Pest Control               | 35(c)  | 35(c)  | No pests allowed in production areas. Effective measures will be taken to exclude pests.   | Have allowed for "Pest Detecting Dogs"; updated terminology to be all encompassing  |
|                     | Sanitation                 | 35(d)  | 35(d)  | All food contact surfaces, utensils shall be cleaned as frequently as necessary to protect against contamination   | No Significant Changes  |
|                     | Food Contact Surfaces      | 35(d1) | 35(d1) | Maintained in a sanitary manner and sanitized as needed  | Made specific to low moisture products  |

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|                                  | Wet Processing     | 35(d2) | 35(d2) | Cleaned and sanitized prior to use and whenever they become soiled   | Added wording about allergen cross contact  |
|                                  | Non Food Contact   | 35(d3) | 35(e ) | Cleaned as frequently as necessary to protect against contamination of food.   | Changed to a requirement  |
|                                  | Single Service     | 35(d4) | 35(d3) | Single use equipment/utensils shall be disposed of immediately to protect from contamination   | Required to be stored in a way to not pose a threat to cross contamination  |
|                                  | Sanitizing Agents  | 35(d5) |        | Used according to directions and adequate to sanitize the equipment in use   | REMOVED   |
|                                  | Portable Equipment | 35(e ) | 35(f)  | Stored in locations that do not pose a contamination risk and protected against contamination  | Contamination during transport and potential for cross contamination were added.  |
| Sanitary Facilities and Controls | Water Supply       | 37(a)  | 37(a)  | Sufficient supply and adequate source; suitable temperature and if under pressure, does not pose a threat to food or food contact surfaces   | No Significant Changes  |
|                                  | Plumbing           | 37(b)  | 37(b)  | Adequate in size and design and maintained to:   | No Significant Changes  |
|                                  | Sufficient Water   | 37(b1) | 37(b1) | Carry sufficient quantities throughout the plant   | No Significant Changes  |
|                                  | Sewage             | 37(b2) | 37(b2) | Properly convey sewage and liquid disposable waste from the plant  | No Significant Changes  |
|                                  | Supply             | 37(b3) | 37(b3) | Avoid being a contaminant to food, water supplies, equipment or utensils   | No Significant Changes  |
|                                  | Floor Drainage     | 37(b4) | 37(b4) | Provide adequate floor drainage to all areas   | No Significant Changes  |
|                                  | Backflow           | 37(b5) | 37(b5) | No backflow from cross connections, piping systems that discharge waste and piping systems that carry water for food and food manufacturing  | Standing water should be minimized  |
|                                  | Sewage Disposal    | 37(c ) | 37(c ) | Done through adequate sewerage system or disposed through other adequate means   | Minor wording clarification   |
|                                  | Toilet Facilities  | 37(d)  | 37(d)  | Shall be made available and be maintained in a sanitary condition, in good repair at all times, provide self closing doors, and not open immediately into a production area.   | Removed the guidance about how to comply  |
|                                  | Hand Washing       | 37(e ) | 37(e ) | Shall be adequate and conveniently located with hot water and: be located at entry points into production; have effective cleaning and sanitizing preparations; towels or drying devices, water control valves that do not pose a contamination risk, posted hand washing signs and garbage pails. | Reworded to just state that handwashing facilities must be provided to ensure an employees hands are not a source of contamination. |

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|                                | Rubbish & Offal Disposal              | 37(f) | 37(f)  | Shall be conveyed, stored and disposed of in a way to minimize odor and waste becoming a contaminant.                       | No Significant Changes  |
| Equipment and Utensils         | Design of Equipment and Utensils      | 40(a) | 40(a1) | Made of material that is cleanable and maintainable; Preclude adulteration with foreign materials, installed appropriately. | Broke out the original 40(a) into individual requirements. Change wording for this one to include Designed of a material and workmanship to be cleanable and properly maintained. |
|                                | Design and Use of Equipment & Utensil |       | 40(a2) |   | Design and construction must preclude the adulteration of food with lubes, fuel, metal, water, etc.   |
|                                | Installation & Maintenance            |       | 40(a3) |   | Equipment installed and maintained to facilitate cleaning of equipment and all adjacent spaces  |
|                                | Corrosion Resistant                   |       | 40(a4) |   | Must be corrosion resistant when food contact   |
|                                | Food contact surface/ non toxic       |       | 40(a5) |   | Food contact surface made from non toxic substance and designed to withstand the environment  |
|                                | Maintenance of food contact surface   |       | 40(a6) |   | Made to protect against cross contact contamination or any other source of contamination  |
|                                | Seams                                 | 40(b) | 40(b)  | Smoothly bonded and maintained free from contamination and foreign materials  | Minimize accumulation of food, dirt and organic matter was added  |
|                                | Equipment                             | 40(c) | 40(c)  | Constructed of appropriate materials and maintained in a clean and sanitary manner  | Added that it applies to areas where food is manufactured, processed, packed and held   |
|                                | Holding/Conveying                     | 40(d) | 40(d)  | Constructed of appropriate materials and maintained in a clean and sanitary manner  | No Significant Changes  |
|                                | Freezer/Cold Storage                  | 40(e) | 40(e)  | Fitted with an means of measuring temperature and be maintained   | Removed the requirement for an alarm  |
|                                | Instruments                           | 40(f) | 40(f)  | Shall be accurate and adequate in number for their designated use   | No Significant Changes  |
|                                | Compressed Air                        | 40(g) | 40(g)  | Shall not pose a threat to food and not contaminated with unlawful indirect food additives                                  | No Significant Changes  |
| General Processes and Controls | Adequate Sanitation                   |       | 80(a1) |   | All operations in manufacturing, processing, packing and holding (including receiving, inspection, transport and segregating) be done according to sanitary principles.           |
|                                | Quality Control Operations            |       | 80(a2) |   | QC operations used to ensure food is suitable for human consumption and food packaging materials are safe.  |

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|                        | Supervision of Sanitation                  |        | 80(a3) |   | All sanitation activities be done under supervision of one or more qualified individuals   |
|                        | Production Procedures                      |        | 80(a4) |   | Precautions taken to ensure production procedures do not contaminate or cross contaminate product.   |
|                        | Quality Testing                            |        | 80(a5) |   | Procedures used to identify sanitation failures or possible cross contamination of food.   |
|                        | Contaminated Food                          |        | 80(a6) |   | Contaminated food that is adulterated is rejected, treated or reprocessed to eliminate contamination.  |
| Processes and Controls | Inspection, Segregation & Handling of RM's | 80(a1) | 80(b1) | Raw materials (RM) will be inspected upon receipt and again prior to use. They will be segregated and stored in a way to keep them suitable for use. Raw materials will be washed prior to use if applicable and water will be of sanitary quality. | Containers and carriers of RM's need to be inspected upon receipt to ensure no contamination; cross contact and deterioration have been added. |
|                        | Microorganisms in RM's                     | 80(a2) | 80(b2) | RM's shall either not contain levels of microorganisms or be pasteurized or treated with a kill step.   | Deleted the guidance on how to comply; no other significant changes  |
|                        | Natural Toxins in RMs                      | 80(a3) | 80(b3) | RM's shall be free of natural toxins such as aflatoxin and meet the FDA requirements. COA or Supplier guarantee may be used.  | Deleted the guidance on how to comply; no other significant changes  |
|                        | Pest, Microorganisms and FM in RMs         | 80(a4) | 80(b4) | RM's and rework shall comply with FDA's defect levels for pests, microorganisms and foreign material. COA or Supplier guarantee may be used.  | Deleted the guidance on how to comply; no other significant changes  |
|                        | RM's and Rework                            | 80(a5) | 80(b5) | RM's and rework shall be maintained in bulk or in containers constructed of sanitary materials and protected against contamination and adulteration. Rework shall be labeled.   | No Significant Changes   |
|                        | Frozen RMs                                 | 80(a6) | 80(b6) | Frozen RMs shall be kept frozen and thawed in a way to prevent adulteration or contamination.   | No Significant Changes   |
|                        | Liquid and Dry RMs                         | 80(a7) | 80(b7) | Liquid or dry RMs received and stored in bulk form shall be protected from contamination.   | No Significant Changes   |
|                        | Allergens                                  |        | 80(b8) |   | Allergens and rework that contain allergens need to be held to prevent cross contact   |

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|  | Equipment, Utensils and FP containers | 80(b1)  | 80(c1)  | Equipment, Utensils and FP containers shall be kept free of contamination and cleaned if necessary.   | Equipment must be taken apart for thorough cleaning and reflects all stages in the process, not just FP  |
|  | Manufacturing and Storage             | 80(b2)  | 80(c2)  | Manufacturing, packaging and storage shall be done to reduce contamination. Monitoring of physical factors such as time, humidity, aw, pH, pressure, flow rate and manufacturing operations such as freezing, dehydration, etc. is done to ensure that poor conditions do not contribute to decomposition or contamination. | Added reference to allergen cross contact and deterioration; Deleted reference about how to comply   |
|  | Manufacturing Food                    | 80(b3)  | 80(c3)  | Food that can support the growth of microorganisms will be: maintained at refrigeration levels of 45 Degrees F or below; maintained frozen; Maintained at 140 degrees F or above; or heat treated or acidified to destroy mesophilic microbes for hermetically sealed foods.  | Deleted reference on how to comply; Guidance document will have the references   |
|  | Manufacturing Controls                | 80(b4)  | 80(c4)  | Measures taken to destroy microbes such as sterilizing, pasteurizing, etc. shall be done under conditions to prevent food from being adulterated.   | No Significant Changes   |
|  | Work in Process                       | 80(b5)  | 80(c5)  | Will be protected against contamination   | Added reference to cross contact and growth to undesirable organisms   |
|  | Finished Foods                        | 80(b6)  | 80(c6)  | FP shall be protected from RMs and shall not be handled simultaneously in receiving, loading or shipping areas.   | FP protected from cross contact and contamination from raw materials, ingredients or refuse. Also added conveyed materials protected from cross contact. |
|  | Containers                            | 80(b7)  | 80(c7)  | Containers, equipment and utensils shall be constructed, handled and maintained in a sanitary manner.   | Deleted guidance on how to comply and reference cross contact  |
|  | Foreign Material Control              | 80(b8)  | 80(c8)  | Protection from foreign material shall be maintained using metal detection, strainers, screens, etc.  | Deleted guidance on how to comply foreign reference cross for  |
|  | Adulteration                          | 80(b9)  | 80(c9)  | Adulterated product shall be disposed of or reconditioned in a manner that does no pose a threat and shall be reexamined.   | Reconditioning was clarified to allow for re-examining of product for some instances but not as a means of adulteration control                          |
|  | Mechanical Manufacturing              | 80(b10) | 80(c10) | Washing, peeling, grinding, etc. activities will be done in a way to protect against contamination.   | Added requirement for protection against drips, draining and drawing of contamination into the product.  |

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|  | Heat Blanching     | 80(b11) | 80(c11) | Done according to temperature and hold times that do no promote thermophilic growth and contamination.  | Added requirement for adequate operating temperatures and periodic cleaning of equipment            |
|  | Prepared Foods     | 80(b12) | 80(c12) | Batters, breading, sauces, etc. shall be treated or maintained to protect against contamination. One or more of the following will be done: use RMs free of contamination; Employ adequate heat process; Adequate time and temp controls; Physical protection of components; cooling to an adequate temp during manufacturing; Disposing of batters at appropriate intervals to reduce growth | Protection against cross contact added; Deleted recommendation on how to comply; gave some examples |
|  | Filling/Assembling | 80(b13) | 80(c13) | Filling, assembling, packaging and other operations will be protected from contamination. This includes: Use of control and CCP points; adequate cleaning and sanitizing; using suitable containers for packaging; providing physical protection from contamination; and using sanitary handling procedures.  | Protection against cross contact added; Deleted recommendation on how to comply                     |
|  | Dry Foods          | 80(b14) | 80(c14) | Foods relying on water activity to prevent growth will employ one or more of the following: monitoring of water activity; controlling soluble solids; protection of FP from moisture.   | Deleted recommendation on how to comply; gave some examples   |
|  | Acidified Foods    | 80(b15) | 80(c15) | Acid and acidified foods that rely on pH to prevent growth will employ one or more of the following: monitoring of pH of RMs, in process and FP; controlling the amount of acid or acidified food added to low-acid foods.  | Deleted recommendation on how to comply   |
|  | Ice                | 80(b16) | 80(c16) | Ice that comes in contact with food shall be made from safe water.  | No Significant Changes  |
|  | Animal Feed        | 80(b17) |         | Manufacturing of human food shall not be used for animal feed unless there is no reasonable possibility for the contamination of the human food.  | DELETED   |

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| Warehousing & Distribution     | Warehousing & Distribution     | 93     | 93  | Finished goods will be protected against physical, chemical and microbial contamination and against deterioration of the food and the container                        | Deleted guidance on how to comply; cross contact added  |
| Natural or Unavoidable Defects | Natural or Unavoidable Defects | 110(a) | 110 | FDA establishes maximum levels for defects produced under cGMPs and uses these levels in deciding whether to recommend regulatory action                               | Deleted guidance of how to comply; reference cross contact; Changed microbial to biological and added radiological. |
|                                | Action Levels                  | 110(b) |     | Action levels have been established and change with new technology or new information  | No Significant Changes  |
|                                | Compliance                     | 110(c) |     | Food outside the action levels can be considered adulterated and manufacturers, distributors and holders of food should utilize good quality control to limit defects. | No Significant Changes  |
|                                | Mixing of Defects              | 110(d) |     | Mixing of foods from a high defect lot with a lower is not permitted and renders the final food adulterated.   | No Significant Changes  |
|                                | Compilation of Defect Levels   | 110(e) |     | A list can be obtained upon request from the Center for Food Safety and Applied Nutrition.   | Added internet address  |

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|  | Same concept but changed location |
|  | Change                            |