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*Dietary Supplement & Functional Foods Program*

NSF GMP Guidance Document  
21CFR § 11/111  
NSF/ANSI 173 Section 8

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**SUBPART B 111.10 – 111.14: PERSONNEL**

**Question 1 CFR 111.10**

*Procedures have been established that define work requirements for personnel to prevent microbial contamination from illness hygienic practices.*

- a. A written procedure shall exist and be current stating that personnel with medical conditions such as open lesions or infected wounds will be removed from the manufacturing process so as to prevent product adulteration during manufacturing or storage. The procedure shall state that such health conditions will be reported to supervision.
- b. Inspection verifies that such workers are not in areas where adulteration could occur.
- c. Personnel shall be trained on the written procedure and knowledgeable of the disease control policies

**Question 2 CFR 111.10**

*Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated.*

- a. A written dress code shall exist and be current stating appropriate attire for workers, supervisors, managers and visitors to all parts of the production, storage, packaging and testing facilities.
- b. Outer garments shall be donned prior to entering the facility and shall not be worn outside the production facility or home. Therefore proper changing areas are required. Outer garments shall have long sleeves and have secured fasteners. Above waist pockets (or carrying items in pockets) should be avoided.
- c. Outer garments shall not be worn into restroom and appropriate hooks should be provided.
- d. A written procedure shall exist and be current describing hand washing requirements including methods and frequencies. The procedure shall also cover glove use and hand sanitizers if used.

**Question 3 CFR 111.10**

*Procedures for removal of jewelry and other items or appropriate coverings.*

- a. A written procedure shall exist and be current describing wearing of jewelry. Jewelry if allowed must be secured to prevent product adulteration. Hand jewelry must be covered if it cannot be removed.

**Question 4 CFR 111.10**

*Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources.*

- a. A written procedure shall exist and be current excluding the use of tobacco products, consumption of food, gum, drink or medicine from production areas.
- b. A written procedure shall exist and be current describing what types of items cannot be taken into production areas including personal effects or clothing. The procedure should cover the prevention of personal care products from entering product.

**Question 5 CFR 111.10**

*Appropriate change rooms are available if needed and there is adequate storage of personal effects.*

- a. Change rooms if needed are orderly and clean. Procedures cover cleaning change rooms.
- b. Training has occurred for all the above policies

**Question 6 CFR 111.12**

*Personnel must be qualified and have adequate training, experience and/or education necessary to perform job functions.*

- a. All personnel shall have written job descriptions, which include job requirements and reporting structure. Job descriptions should follow good documentation practices including revision control and appropriate sign offs.
- b. All personnel including management shall receive annual GMP training and education to perform their assigned functions.
- c. Training comprehension for annual GMP training is required. Comprehension can be shown by routine questioning of employees to determine understanding of GMPs as they relate to their job function.
- d. Temporary workers shall receive documented basic GMP training prior to beginning work.

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**Question 7 CFR 111.12**

*Quality responsibilities are distinct and separate from operations.*

- a. A clear organization chart shall be available that is current and up to date.
- b. Quality control department/personnel shall exist and duties shall be documented (specific duties listed in Subpart F). The Quality Manager shall not report directly to the Production Manager to ensure that quality decisions can be made independent of production decisions. Consideration will be given for small plants where individuals have multiple organizational responsibilities

**Question 8 CFR 111.13**

*Procedures have been established to define the requirements for personnel who will supervise activities.*

- a. Supervisors shall have written job descriptions, which include job requirements and reporting structure. Job descriptions should follow good documentation practices including revision control and appropriate sign offs.
- b. Assure each department has designated and qualified supervisors.
- c. Procedures for supervisors, managers, and other levels of supervision and responsibility exist. The procedures should outline the requirements to be in a supervisory position and also periodic assessment and procedures to remove a person from supervisory responsibilities if they do not sustain the qualification.

**Question 9 CFR 111.13**

*Personnel who are designated as supervisors are qualified and have written requirements.*

- a. If multiple shifts of operation are used, designated trained supervisors are required

**Question 10 CFR 111.14**

*Procedures have been established and records are maintained documenting compliance to these procedures.*

- a. A written procedure shall exist and be current outlining the training policy and program. The procedure shall include how training is conducted for new hires, annual training for all personnel and contractor training if applicable. The training program should include training topics and frequencies as well as forms for documenting training.
- b. Training and procedures shall be available in appropriate languages.
- c. Training documentation shall include a roster of who attended, date of training, subject matter taught and the name of the trainer.

**Question 11 CFR 111.12**

*Job descriptions are available for all personnel and personnel have received GMP and appropriate training for their assigned functions.*

- a. All personnel shall have written job descriptions, which include job requirements and reporting structure. Job descriptions should follow good documentation practices including revision control and appropriate sign offs.
- b. All personnel including management shall receive annual GMP training and education to perform their assigned functions.
- c. Training comprehension for annual GMP training is required. Comprehension can be shown by routine questioning of employees to determine understanding of GMPs as they relate to their job function.
- d. Temporary workers shall receive documented basic GMP training prior to beginning work.

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**SUBPART C 111.15 – 111.23: PHYSICAL PLANT AND GROUNDS**

**Question 12 CFR 111.15a**

*Grounds have been properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc.*

- a. No areas of clutter shall exist around the plant's perimeter that could be pest harborage areas.
- b. Vegetation around the outside perimeter of the facility shall be kept to a minimum. Individual situations shall be evaluated based on pest control system.
- c. Roads, docks, parking lots and yards shall be clean, in good repair and minimize dust.
- d. Standing water shall not be evident around plant's perimeter.

**Question 13 CFR 111.15a4**

*Waste treatment and disposal is adequate and does not provide a source of potential contamination.*

- a. Outside waste containers shall be covered and emptied to prevent overflowing. Inorganic containers are not required to be covered.

**Question 14 CFR 111.15a5**

*Production Facility is maintained in a clean and sanitary condition and in a proper state of repair.*

- a. Maintenance program exists for the facility.
- b. Cleaning procedures cover all areas of the facilities and grounds.

**Question 15 CFR 111.15**

*Entrances to the facilities are properly controlled and maintained to prevent contamination.*

- a. All doors to the outside shall fit tightly (i.e. no visible light around or under doorway) and remain closed when not in use.

**Question 16 CFR 111.15c**

*Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and adequate under the conditions of use.*

- a. A written procedure shall exist and be current concerning chemical control. The procedure should outline the purchasing policy for chemicals, list approved chemicals, give quality controls on purchasing to ensure that only approved chemicals are purchased and describe chemical usage guidelines (including concentrations and areas where chemicals can be used).

**Question 17 CFR 111.15c3**

*Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been identified, used, and held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials.*

- a. All chemicals shall be stored in labeled containers and used for their intended purpose only.
- b. All chemicals shall be stored away from product and equipment to prevent contamination through spills. All spills should be cleaned up immediately.
- c. All chemicals shall be stored with like substances. Food grade chemicals shall not be stored with non-food grade chemicals.

**Question 18 CFR 111.15d1,2**

*Procedures have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc.*

- a. Exterior openings (windows, ventilation etc.) are screened or sealed to protect against pests.
- b. It is required that a licensed pest control agent provides pest control. If internal personnel are used, then the same level of expertise shall be provided. The up to date license, contract and insurance shall be on file.
- c. The licensed agent is expected to provide aggressive support to plant pest control, housekeeping, sanitation and maintenance programs as they relate to potential pest harborages or conditions susceptible to pest infestations. Any conditions noted by the pest agent, shall have documented corrective action implementation. Company personnel shall review all reports.
- d. The pest control agency should provide a report outlining the methods used in developing the placement of traps and the logic used in creating the pest control program.

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- e. The pest control system shall include at a minimum bait traps (only located outside of buildings), interior pest traps (glue boards or other non-chemical means) and insect lights. Other methods can be used. A map of all units (lights and traps) shall be kept up to date.
- f. Exterior doorways shall have traps on either side of the door opening inside the building.
- g. All traps shall be marked or fixed to a location to prevent movement.
- h. Pest traps and lights shall be monitored for activity. The activity shall be reported in a written document including where the activity occurred, what type of activity occurred and any corrective actions taken. If activity warrants, frequency may be increased. Traps shall be checked at least monthly. High activity may warrant more frequent checks.

**Question 19 CFR111.15d3**

*Pest control procedures have been established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc.*

- a. Use of chemical sprays is not typical inside production facilities. If chemical means are needed because of pest infestations, then procedures shall exist outlining that all production shall cease and all product be stored in a means to prevent adulteration. Production records shall reflect adherence to this policy during chemical applications. Logs of applied chemicals shall be kept. MSDS's for all applied chemicals shall be kept.

**Question 20 CFR 111.15e**

*The water supply is safe and sanitary and under suitable temperature and pressure. Water that may contact a product contact surface or is in fact a component must meet U.S. Federal, State and Local requirements for drinking water.*

- a. Water supply shall be safe and of adequate temperature and pressure at all points of use in the facility which can be determined by checking for flow at various faucets or other points of use.
- b. If the plant has more than one water system (potable, non-potable, treated, DI etc.) then piping shall be labeled. Facility Plumbing and Water Line Diagrams should be available.
- c. Water used as a component (i.e. as an ingredient or that contacts product contact surfaces), must meet Federal, State and local requirements (at a minimum EPA NPDW 40 CFR Part 141) at point of use. Non-U.S. firms must meet equivalent standards.
- d. A written water-testing program shall exist and be current for water used as a component. The program shall outline testing frequency, sample locations and testing requirements. Sampling shall occur at point of use and vary from time to time if multiple points of use exist. Testing at a minimum should include weekly micro testing (total plate count, yeast & molds) or minimum chlorine level as outlined in 40 CFR part 141. Additional testing may be needed to ensure water standards are met.
- e. If in house manufactured ice is used for product contact, then the ice shall be tested for microbiological potability semi-annually. Purchased ice shall have a certificate of potability. Maintenance of ice machine shall have written procedures.
- f. If steam is product contact, then boiler treatment chemicals shall be food grade.

**Question 21 CFR 111.15f3 & CFR111.15e**

*Water sources do not act as a potential source of contamination of the dietary supplement, either due to water purity or due to the configuration and construction of the water delivery system.*

- a. Water piping shall be so configured that it does not become a source of contamination (elimination of dead end piping and proper drainage).

**Question 22 CFR 111.15f**

*Plumbing is of adequate size and design for intended usage.*

- a. Piping and plumbing throughout the facility shall not be leaking or damaged.
- b. All plumbing should be appropriately trapped to prevent back flow.
- c. Drip legs should be piped into floor drains (allowing for siphon breaks). Drip legs shall not drip onto the floor.
- d. Standing water shall not be evident within the manufacturing facility.

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**Question 23 CFR 111.15g**

*Sewage and waste disposal is properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc.*

- a. Sewage shall be disposed into a properly maintained and approved sewage system that complies with local regulatory requirements. Process and sanitary sewers shall be plumbed separately.
- b. Sewage lines shall not vent inside of buildings.

**Question 24 CFR 111.15f4**

*Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.).*

- a. All areas requiring wet cleaning should have adequate floor drains.
- b. All drains shall be covered with grating and be free of debris.
- c. Drains shall be part of cleaning procedures and be odor free.
- d. Drains shall drain properly and not back up or contain standing water.

**Question 25 CFR 111.15f5**

**Backflow and cross-connection prevention is in place.**

- a. The city water or water supply to the plant shall have a backflow prevention device at the plant's connection point. An annual PM is required for checking the backflow system.
- b. All hose drops or points of use where product siphoning could occur shall have backflow prevention. An annual PM is required for checking backflow devices.

**Question 26 CFR 111.15h**

*Bathrooms are provided and are of adequate number and location.*

- a. Bathroom shall be available to all workers, well lit, functional and stocked.
- b. Bathrooms shall be clean and sanitary at all times. Routine documented cleaning must take place.
- c. Bathrooms must have signs directing employees to wash hands before returning to work
- d. Bathroom doors shall be self-closing and not open into operation areas where product is exposed.
- e. Bathrooms shall vent mechanically to the outside

**Question 27 CFR 111.15h**

*Bathrooms and wash facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc.*

- a. Routine documented cleaning of bathrooms and hand wash facilities must take place
- b. Hand washing facilities cannot be used to clean utensils or equipment.

**Question 28 CFR 111.15i**

*Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing of personnel.*

- a. Hand washing facilities furnished with tempered water shall be located where employees are required to wash hands.
- b. Hand washing facilities shall have hands free faucets. Hands free can be foot operated, sensor operated or have long handles that can be controlled with the arm or wrist.
- c. Air dryers or single use sanitary towels shall be provided.
- d. Liquid or single use soap shall be provided.
- e. Signs shall be posted instructing employees to wash hands before returning to work.

**Question 29 CFR 111.15j**

*Solid waste and trash are disposed of appropriately and not allowed to accumulate.*

- a. Refuse, garbage, waste, and debris from all areas must be promptly and adequately removed.

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**Question 30 CFR 111.15j2,3**

*Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc.*

- a. Refuse receptacles in restrooms and production areas shall be containers designated only for refuse. Modified product containers shall never be used for refuse.
- b. Receptacles shall prevent pest harborage and be covered.

**Question 31 111.15 j4**

*Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc.*

- a. Procedures cover hazardous waste if needed. Hazardous waste is handled separately from other waste streams.

**Question 32 CFR 111.15k**

*Sanitation supervisors have been assigned and are qualified.*

- a. A job description shall exist and be current for the sanitation manager (or be part of individual job descriptions if duties are shared).
- b. The sanitation manager and all employees who perform sanitation shall be knowledgeable and trained on all housekeeping/sanitation procedures.

**Question 33 111.16**

*Procedures have been established for cleaning of the plant.*

- a. Periodic internal audits of sanitary practices shall be conducted at a minimum on a monthly basis.
- b. Written procedures for maintaining and cleaning of grounds and facilities shall be written and followed. Cleaning of facilities and grounds must be documented.
- c. A written procedure shall exist and be current covering facilities (including warehouse, rooms, areas) cleaning. This procedure shall cover the methods, frequencies and chemicals to be used when cleaning these areas and include how the cleaning shall be documented.
- d. Procedures have been established for waste handling and disposal frequency (chemical, biological, hazardous, and solid wastes).

**Question 34 CFR 111.20a**

*All facilities are of adequate size, construction, and design for their intended use.*

- a. A current Facility Diagram/Floor Plan should be available. Review the diagram during the inspection.
- b. Plant design in areas where product is routinely open, shall have cleanable surfaces. Painted and/or wood surfaces should not be used in areas of product or equipment contact.
- c. Ledges in product contact areas shall be minimized to prevent dust accumulation.
- d. Gowning areas shall be located at the entrance to required production areas and should be designed to prevent entrance or exit without gown changing.
- e. Assure adequate control between areas that have restrictions and unrestricted areas.
- f. Elevated platforms or catwalks shall be cleanable and designed to prevent contamination into processes located below the platforms.
- g. The maintenance shop area shall be kept in a clean and orderly manner. The shop should be physically separated from production areas so contamination cannot occur.

**Question 35 CFR 111.20b**

*There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding.*

- a. All product stored in warehouse facilities shall be enclosed in tight fitting enclosures.
- b. No product shall be stored on the floor for prolonged periods. All materials (packing materials, raw materials, finished products, etc.) shall be stored at least 6 inches off the floor (at least at pallet height). All racking should be at a minimum 12 inches from perimeter and interior walls to facilitate cleaning.

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**Question 36 CFR 111.20c**

*There are adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials.*

- a. Warehouse facilities shall be devoid of dust and debris and free from pest indications.
- b. Hazardous chemicals shall not be stored near ingredients, components or finished goods.

**Question 37 CFR 111.20c1**

*Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, dietary supplements, packaging, and labels that will be used.*

- a. Written procedures shall exist and be current describing operation flow of goods and how/where goods shall be stored and segregated. Segregation is adequate throughout the facility.

**Question 38 CFR 111.20c2**

*Areas have been provided for quarantine and release of materials to be used in the manufacture, packaging, or labeling of dietary supplements.*

- a. Methods for controlling status of goods are used which may include computerized inventory systems.

**Question 39 CFR 111.20c3**

*Areas have been provided to separate the manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements.*

- a. Procedures and controls must be in place to ensure no cross-contamination occurs between dietary supplements and foods, cosmetics or pharmaceuticals. Cleaning procedures should be validated.

**Question 40 CFR 111.20c4,5,6,7**

*Separate or defined areas exist for laboratory analysis and holding of laboratory supplies and samples, cleaning of contact surfaces, packaging and labeling, and holding of components or dietary supplements.*

**Question 41 CFR 111.20d1i**

*Walls, floors, ceilings can be adequately cleaned and kept in good repair*

- a. All rooms where product contact occurs shall have walls, ceilings, floors and work surfaces that can be cleaned and sanitized. Seams should be minimized in wall and ceiling coverings.
- b. Floor to wall joints shall be sealed with concave or cove baseboards or bumpers.
- c. Ceilings shall be constructed of smooth, non-porous, non-absorbent, cleanable material. Acoustic tile ceilings are not to be used in product contact rooms, the panels shall be FRP or HDPE grade or equivalent material. The grid systems shall be on a cleaning schedule.
- d. Floors in product contact areas shall not have exposed aggregate, cracks, peeling coating or broken areas. Floors shall be kept clean and dry.
- e. Ceiling and wall penetrations shall be sealed.
- f. Interior wall and ceiling surfaces are free from signs of moisture, damage, insects/pests, mold/mildew, etc.

**Question 42 CFR 111.20d1ii**

*Fixtures, ducts, piping, etc. are kept clean, do not drip or leak or provide a source of condensation that could contaminate components, products, or contact surfaces.*

- a. Vents, fans and gratings in product contact areas shall be on a cleaning schedule.
- b. There shall be no evidence of water leaks.
- c. Piping, joists and bracing shall be free of dust and contaminants.

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**Question 43 CFR 111.20d1iii**

*Adequate ventilation and airflow is provided in all areas of the facility.*

- a. Excessive dust buildup from powdered products should be minimized by dust collection.
- b. Documented systems exist to ensure dust collection fines and or vacuum fines shall not be recycled into finished goods..
- c. Heating and ventilation systems shall be provided to maintain sanitary conditions. Condensation on walls or ceilings shall be prevented. A PM program shall exist for all HVAC units
- d. Air filtration system must be in place to prevent cross-contamination or adulteration of product.

**Question 44 CFR 111.20d1iv**

*Temperature and humidity control equipment is of adequate design for its intended function and is functioning properly.*

- a. If temp and humidity is monitored, then ranges shall be established and documented corrective actions implemented if temperature deviates from accepted range. Such devices shall be part of calibration or PM programs.

**Question 45 CFR 111.20d1v**

*Working areas have adequate access and space, aisles are clear, etc. to allow for persons to perform their duties and protect against contamination or mix-ups.*

**Question 46 CFR 111.20e**

*Adequate lighting is provided in all production areas, examination areas, where equipment is cleaned and examined, etc.*

**Question 47 CFR 111.20f**

*For lighting that is suspended or located above areas where materials or equipment are exposed are of adequate construction or lighting type to prevent contamination (use of safe-lights, fixtures, etc.).*

- a. All lighting in areas with exposed product shall be shatter proof. Shatterproof includes plastic bulbs or glass bulbs fitted with plastic shields.

**Question 48 CFR 111.20g**

*In areas where open vessels are used, there is adequate protection against contamination, e.g. use of protective coverings, physical location, use of skimming equipment, use of screening, etc.*

- a. All tanks and hoppers shall be equipped with lids or covers. Tanks and hoppers shall be covered when not actively being filled.

**Question 49 CFR 111.20h**

*Production areas do not provide a haven for pests, pest infestation, filth, etc. (adequate screening and other measures are used).*

- a. No harborage areas exist and facility is tidy and orderly.

**Question 50 CFR 111.23**

*Records have been maintained for plant cleaning, pest control, and water quality (where required) and in accordance with Subpart P.*

- a. Procedures have been established for cleaning of rooms and areas including frequency, inspection, and approved cleaning materials.
- b. All cleaning is documented.

**Question 51 111.23**

*Records have been maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15(e)(2).*

- a. Water test results are kept and current based on testing procedures (water as a component must have test results from point of use).

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**SUBPART D 111.25 – 111.35: EQUIPMENT AND UTENSILS**

**Question 52 CFR 111.25a,b**

*Procedures have been established for calibration of all instruments, controls, automated, mechanical, and electronic equipment, etc.*

- a. Written procedures shall exist and be current for all equipment (laboratory and production) calibrations. These procedures should describe the frequency of testing, the testing method and the acceptable range of variation.
- b. Procedures should include calibration before each use and documented corrective actions for equipment that must be repaired or replaced.

**Question 53 CFR 111.25c**

*Procedures have been established for the cleaning and sanitization of all utensils and equipment.*

- a. Written procedures shall exist and be current detailing the cleaning, sanitizing and storing procedures for all equipment and utensils. Procedures shall include methods, chemical usage and dilutions and frequencies.

**Question 54 CFR 111.25c**

*Procedures and programs have been established for maintaining equipment.*

- a. The plant shall have a documented preventative maintenance program. The program shall designate equipment with unique identifiers (equipment numbers). The program shall outline what activities shall be completed for the preventative maintenance and the frequency the maintenance shall occur. The system can be paperless, but adequate records shall show that the maintenance was completed as scheduled based on the established frequency.
- b. The PM program shall include auxiliary equipment such as HVAC units, dust collectors, boilers, air compressors and water treatment systems.

**Question 55 CFR 111.27a**

*All equipment and utensils are corrosion resistant, made of nontoxic materials, and of suitable design, construction, and workmanship for their intended use.*

- a. Equipment and utensils that are product contact shall be smooth, inert, impervious, non-toxic and corrosion resistant.
- b. No wood handled or wood part utensils are to be used (including mops, squeegees and brooms).
- c. Non-cleanable materials such as cardboard and tape should not be used.

**Question 56 CFR 111.27a2**

*Equipment and utensils are of appropriate design so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants.*

- a. Condensation, metal fragments or excessive lubrication shall be kept from entering the product.
- b. Equipment shall be free of flaking paint, rust or other contaminants that could become detached and adulterate the product.
- c. Temporary repairs are allowable, but permanent repairs shall be made promptly. Tape, wire, string, cardboard are not acceptable materials for temporary repairs.

**Question 57 CFR 111.27a3iv**

*Equipment and utensils are designed and constructed to withstand the environment in which they are used and do not degrade upon exposure to components, process materials, cleaning agents, etc.*

- a. Conveyor belts shall be impervious, non-absorbent and cleanable. Belts shall be in good condition with no signs of wear, holes or frayed edges.
- b. Gasket material that is product contact shall be non-toxic, non-absorbent, easily cleanable, intact and in good conditions.
- c. Records of gasket maintenance shall be kept as part of PM program.

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**Question 58 CFR 111.27a3v**

*Equipment and utensils protect components and dietary supplements from contamination from any source.*

- a. If tools must be used on equipment during production then the tools shall be clean and prevent cross contamination. Tools are not to be stored on top of equipment, ledges or electrical boxes but should be stored in cabinets or outside of product contact areas.
- b. Storage of cleaned equipment and utensils shall preclude adulteration from other activities in the area or airborne contamination.
- c. Utensils for cleaning or for product contact shall have specific, convenient and sanitary storage hangers or shelves. Items shall not be stored on the floor, pallets or against painted surfaces.
- d. Mops are not to be stored in water but hung up to dry after use. Mop heads shall be part of cleaning schedule.
- e. Water or air hoses shall be stored off the floor. Product transfer hoses shall be drained, stored off the floor and capped.
- f. Brooms should not be a source of contamination and should be designated for area of use.
- g. Facilities and/or equipment and utensils shall be designed to prevent product or product contact surfaces from coming in contact with non-product contact areas such as floors and walls.
- h. Bulk unload hose systems shall be labeled, capped and secure.
- i. Ancillary piping should be labeled as to contents to prevent wrong connections.

**Question 59 CFR 111.27a4**

*Equipment and utensils are constructed as seamless, or if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants.*

- a. Equipment welds and seams shall be polished and smooth to prevent accumulation and facilitate cleaning.

**Question 60 111.27v**

*Equipment and utensil surfaces are inspected at routine intervals for signs of wear, damage, etc.*

- a. Inspect the equipment interior for damage, rusting, rouging (in stainless steel equipment), pitting or gouging, stains, uncleanliness, etc. Interior surfaces should be clean, smooth (seamless) and in good condition.
- b. Inspect the equipment exterior for damage, peeling paint, debris, dust, oils, spilled chemicals/materials, etc. Exterior surfaces should be well maintained, clean, and should not be a source of possible contamination.
- c. Inspect all hatch covers, exposed gaskets, etc. for damage, cleanliness, etc.
- d. Equipment shall be maintained and not show signs of excessive wear. If excessive wear is seen, then a maintenance program shall be established to ensure product is not adulterated.

**Question 61 CFR 111.27a5**

*Equipment such as freezers, refrigerators, etc. that are used to hold components or dietary supplements must be functioning properly and adequately designed.*

- a. If product storage requires cold or freezer storage, special equipment or rooms shall be available. If cold storage units are used, then alarming or regulating temperature devices are required. Temperature record logs shall be kept. Temperature ranges shall be established and documented corrective actions implemented if temperature deviates from accepted range. Such devices shall be part of calibration or PM programs.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 62 CFR 111.27a6**

*Instruments and controls that are used in all areas must be accurate and precise (calibrated where necessary), maintained, and adequate in number.*

- a. Instruments (laboratory and operational) shall be part of a calibration and/or PM program. Ancillary gauges, instruments, etc. are appropriately installed for function and calibrated.
- b. Calibration records shall include
  1. Identity of instrument or control
  2. Date calibration is performed
  3. Identity and certification of compliance of any reference standard
  4. Calibration procedure that was used including the calibration limits or specifications
  5. Calibration readings or readings found
  6. Recalibration method and readings found (if required)
  7. Initials of the person performing the calibration
- c. Annual calibration of operational equipment, measuring and metering devices such as thermometers, scales, flow meters, timers, speed controls, HPLC, GC, AA, metal detectors, etc. shall be properly completed to assure their accuracy. Equipment shall be calibrated on a frequency that is justified by data, taking into account the type of equipment in question and the required accuracy and precision you need based on how you will be using it.
- d. Scales shall be calibrated by a certified individual at least annually.
- e. Scales shall be evaluated at appropriate weights prior to use. These checks (recording the observed weights) shall be documented.
- f. Test weights shall be calibrated by a certified contractor at least annually, or whenever they are dropped or damaged. Records shall be available. Test weights shall be stored properly off the floor. They should be stored in cabinets or shelves where they are protected against water or potential damage.
- g. Checks of intermediate thermometers against NIST-traceable standards shall be performed at a frequency commensurate with the use of the intermediate thermometer, but at least annually. Full documentation of the calibration of the intermediate thermometers shall be available.

**Question 63 CFR 111.27a7**

*Process gases that are used and contact dietary supplements, components, and contact surfaces must be controlled so as not to cause contamination (e.g. filters).*

- a. Compressed air shall be trapped for condensation at points of use. Air dryers may be used. All components (including traps) should be part of PM program. If compressed air is product contact testing should be completed for micro contamination. If compressed air is used in cleaning, the last step prior to use should be a sanitizing step or micro testing should be completed.

**Question 64 CFR 111.27d**

*All equipment, instruments, utensils, contact surfaces etc. must be maintained, cleaned and sanitized as necessary.*

- a. Documentation of major equipment cleaning must be kept. Documentation should include, date, reference cleaning methods, who performed the cleaning and effectiveness checks.
- b. Cleaning procedures shall be verified and inspected. If visual inspection is difficult or impossible then supplement bioluminescence or microbial testing should be used. Deficiencies and corrective action shall be documented and followed up. Final rinse water for tanks or large vessels should be evaluated to determine if chemical residue has been effectively flushed (water clarity, pH, odor).
- c. A final (or pre-start up) sanitizing step on all product contact surfaces is required. Reusable towels should not be used during the sanitizing step.
- d. Equipment and utensils shall be cleaned prior to contact with different products where cross contamination could occur. For example scoops cleaned during weigh up to prevent cross contamination in bulk containers.
- e. Cleaning of equipment and utensils shall be conducted to prevent contamination from chemical residue.
- f. All equipment taken out for maintenance shall have documented cleaning and sanitizing steps prior to putting back in service.
- g. Equipment and utensil status must be clearly indicated.
- h. Storage of cleaned equipment must preclude contamination.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 65 CFR 111.27d1**

*Equipment, utensils, etc. must be disassembled as necessary to assure maintenance, cleaning, and sanitization.*

- a. Equipment shall be designed to be disassembled or easily cleaned in place. Equipment shall be self-draining.
- b. Equipment shall be installed so that it can be cleaned around and under. In some cases equipment may need to be removable.

**Question 66 CFR 111.27d2**

*Low moisture processing: Equipment, utensils, and contact surfaces are dry and sanitized. If wet-cleaned, drying and sanitization is performed.*

- a. Low moisture areas must remain dry when in use. Dry cleaning is acceptable as long as a sanitizing step is performed.

**Question 67 CFR 111.27d3**

*Wet Processing: Contact surfaces are cleaned and sanitized before use and after any interruptions. If continuous production is performed, cleaning and sanitization is performed at designated intervals.*

**Question 68 CFR 111.27d4**

*Surfaces that do not come into direct contact with components or dietary supplements are cleaned.*

- a. Procedures must be established and followed for cleaning of other process areas (non-product contact).
- b. Dust collection systems shall be part of cleaning schedule. Dust hoods or hoses directly above or adjacent to product shall be maintained clean at all times and not provide a source of cross contamination.

**Question 69 CFR 111.27d5**

*Disposable items (single-service) are stored in appropriate containers; handled, used, dispensed, and disposed of in a manner that protects against contamination.*

**Question 70 CFR 111.27d6**

*Cleaning and sanitizing agents are adequate and safe for their intended use.*

- a. Food grade (as specified on the label or accompanying documentation) chemicals shall be used in all product contact applications (cleaning and maintenance).
- b. NSF Registered proprietary substances and non-food compounds are acceptable when used for their intended purposes.

**Question 71 CFR 111.27d7**

*Portable equipment and utensils are properly stored after cleaning and sanitization.*

- a. Portable equipment and utensils must be stored to prevent airborne contamination (usually bagged once dry). Surfaces used to stored cleaned equipment must be sanitary.
- b. All reusable product containers shall be effectively cleaned, sanitized and inspected prior to use. Storage of containers shall prevent contamination.

**Question 72 CFR 111.30a**

*Automated, mechanical, or electronic equipment must be functioning properly and be adequately designed.*

- a. Equipment design ensures operation to meet product specifications. Such as timing devices on blenders.
- b. Automated, mechanical, or electronic equipment is operated within operating limits and is used for its intended purpose.

**Question 73 CFR 111.30d**

*Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use.*

- a. Procedures and controls are in place for changes implemented in operations. Changes are approved by the Quality Unit. Changes may include removing or installing new equipment.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 74 CFR 111.35b1iii**

*Procedures for maintenance, cleaning, and sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation are maintained.*

- a. In addition, a system for determining and repairing maintenance issues prior to contamination problems arising shall exist (such as a GMP audit, pest activity reports, housekeeping audits etc.).

**Question 75 CFR 111.35b2**

*Equipment logbooks have been maintained for each equipment and include the date of use, and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is in the batch record).*

- a. Chronological records shall be kept that enable research into all activities performed on equipment or areas surrounding production of a batch of product. Records should include names, dates, batch numbers and activities (production, cleaning, maintenance) performed. Logbooks or batch records may be used to keep this data as long as the complete history of the batch can be determined.
- b. Logbooks if used shall be kept up to date and completed as close to real time as possible.
- c. If maintenance occurs as part of daily set up or in other operational functions, this maintenance shall also be logged including operator, date, maintenance performed/chemicals used.

**Question 76 CFR 111.35b4**

*Records are available of calibrations, inspections, and checks of any automated, mechanical, or electronic equipment.*

- a. Calibration and PM records are available for review

**Question 77 CFR 111.35b5**

*Backup electronic files have been maintained of the following: current software programs, outdated software programs that may be necessary to retrieve past records, and data that was entered.*

**Question 78 CFR 111.35b5ii**

*Backup files are an exact and complete record and are secure from alterations, erasures, or loss and damage.*

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART E 111.55-111.95: PRODUCTION AND PROCESS CONTROL SYSTEM**

**Question 79 CFR 111.55**

*Production and process control systems have been implemented for each production process and/or product.*

- a. Controls exist at all critical stages of manufacturing through packaging and labeling to ensure product meets quality specifications and is produced according to the MMR.

**Question 80 CFR 111.60**

*Production and processes have been designed to ensure the quality of the product and the Quality Control Unit has approved the control systems.*

- a. Critical control steps are written, part of the MMR and have been approved by quality.

**Question 81 CFR 111.65**

*Quality Control operations have been identified and implemented.*

- a. Quality personnel are responsible for the following duties:
  1. Approving/rejecting processes, specifications, procedures, controls, tests, results and deviations
  2. Approving documentation for supplier qualification
  3. Approving documentation for ensuring dietary supplements meet identity, strength, purity and composition specs.
  4. Approving test results
  5. Oversight of sampling and retain programs
  6. Determining if specifications are met
  7. Reviewing and approving documentation, documentation practices and revisions
  8. Managing and reviewing change to documents, equipment, facilities
  9. Performing audits and implementing corrective actions
  10. Ensuring procedures are followed and the most current revisions are in place

**Question 82 CFR 111.70**

*Specifications have been established for components, in-process materials, labels, packaging components, and finished product.*

- a. Specification for finished product and packaged finished product may be the same
- b. Specifications for in process steps/products may not be needed if adequate finished product specs have been established
- c. Categories of products or components may have the same specifications.
- d. Specifications must have limits.
- e. Ingredients must have an identity specification
- f. Identity, purity, strength and composition of the finished product must be established by either in process specs or finished product specs

**Question 83 CFR 111.75**

*A system has been established to determine if all specifications that are established have been met.*

- a. Testing plans and protocols must be established to ensure specifications are met. At a minimum raw materials and finished products must have established testing plans and protocols.

**Question 84 CFR 111.75a**

*Components are sampled, tested, and confirmed (released) prior to use in production.*

- a. All ingredients must be tested to verify identity. Organoleptic testing can only be used if the product can be positively identified by this method (organoleptic testing of chopped herbs for example is not acceptable).
- b. Ingredient specifications and/or labels indicate accurate shelf life (if applicable). A system is in place for ensuring that expired ingredients are not used in production. This includes first in first out procedures and procedures for managing raw material expiration or retesting.
- c. Approved raw materials shall be rotated so that the oldest approved stock is used first. These should also include procedures for periodic assessment of the inventory to assure that no adverse conditions exist.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 85 CFR 111.75a2**

*If a Certificate of Analysis (COA) is used to confirm the component, the supplier must be qualified and documentation must be maintained for this qualification.*

- a. COA's may be used for confirming all specifications except identity. COA's must include description of the test used, limits and actual results.

**Question 86 CFR 111.75a2iiD**

*Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification), and procedures for disqualification.*

- a. COA's may only be used for confirming specifications if the supplier has been qualified.
- b. Supplier qualification programs require at a minimum:
  1. A documented process reviewed and approved by quality
  2. The supplier COA results to be confirmed
  3. Periodic re-qualification and disqualification procedures

**Question 87 CFR 111.75b,c**

*Proper testing procedures or programs have been established to determine if in process and finished product specifications for purity, composition, and strength of the dietary supplement have been met.*

- a. A program for verifying finished product meets established specifications must be established. The program may use a skip lot system. The program may use testing results of raw materials and/or in process materials in lieu of testing finished product.
- b. At least one component of the finished product must be tested for identity, purity, strength or composition. This may be part of the skip lot system. If the finished product cannot be tested, raw material and/or in process test results may be used to show finished product compliance.
- c. Justification for the testing program and any exemptions must be kept.
- d. Quality Control must review and approve the documentation.

**Question 88 CFR 111.75e**

*For products that are received for packaging and labeling, visual examinations are performed and documentation is available to determine whether the product meets established specifications.*

**Question 89 CFR 111.75f**

*Packaging and labeling materials are visually examined, at a minimum, and are reviewed against the supplier's invoice to determine conformance with specifications.*

- a. Procedures are established and followed for receipt of packaging goods and labels. Inspection of the component or label is required.

**Question 90 CFR 111.75g**

*Packaging and labeling of the finished packaged and labeled dietary supplement are visually examined, at a minimum, to determine that the correct packaging and labeling has been used.*

**Question 91 CFR 111.75h**

Scientifically valid methods are used and include at least one of the following, a gross organoleptic analysis, macroscopic analysis, microscopic analysis, chemical analysis, or another scientifically valid method.

- a. Scientifically valid methods are used for establishing that specifications have been met.

**Question 92 CFR 111.77**

*Procedures and controls have been established for investigation and handling of materials that do not meet specification requirements.*

- a. Procedures have been established and are followed for handling OOS results or product and deviations.
- b. Rejected components, finished product or bulk product has not been used or distributed. Exceptions may apply for reprocessed materials. All exceptions must follow deviation procedures and be approved by quality.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 93 CFR 111.80**

*Procedures have been established for the collection of representative samples.*

- a. A statistically significant sampling program shall be written and followed for collecting samples without introduction of contamination.
- b. All unique lots of ingredients, in-process product, packaging components, labels, received bulk finished goods, finished goods and packaged finished goods shall be sampled. Documented skip lot programs can be used for all sampling except raw materials.

**Question 94 CFR 111.83**

*Procedures have been established for the collection of reserve samples for each lot of finished material.*

- a. A procedure has been established for collection and storage of retain samples. Only finished products retains are required (raw materials are optional).
- b. Retain procedures include:
  1. Container closure system (same or equivalent to finished product packaging).
  2. Retains must be identified for lot traceability
  3. Storage conditions and time requirement (1 year plus shelf life or 2 years past distribution of last batch)
  4. Quantity of sample (at least twice quantity necessary for conducting all tests)

**Question 95 CFR 111.87**

*The Quality Control Unit conducts all material reviews and makes disposition decisions.*

**Question 96 CFR 111.90**

*Procedures have been established for the handling of unexpected events.*

- a. Procedures exist for recording, investigating and implementing corrective actions when deviations occur.
- b. Procedures should exist for handling emergencies.

**Question 97 CFR 111.90a**

*Reprocessing controls have been established and meet all requirements and have been approved by the Quality Control Unit.*

- a. Reprocessing or reworking procedures have been established for production, packaging and labeling operations. These procedures have been reviewed and approved by quality.
- b. Review reprocessing or reworking records. Verify traceability and controls were in place. Verify quality approved the work prior to commencement. Verify that the completed batch(s) were reviewed for specification compliance and released by quality.

**Question 98 CFR 111.95**

*Records are maintained of specifications, supplier qualification and testing to ensure product meets purity, strength and composition.*

- a. Procedures outlining the receipt, sampling, testing and approval/rejection of all raw materials and bulk-finished goods have been established. Records are kept.
- b. Procedures outline the sampling, testing and approval/rejection of all in process and finished goods have been established. Records are kept.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART F 111.103-111.140: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR QUALITY CONTROL**

**Question 99 111.103**

Procedures have been established for the responsibilities of the Quality Control operations.

- a. Written procedures establish quality duties, responsibilities and authorities. These duties are independent from production.

**Question 100 111.105**

Quality Control Personnel have established roles and responsibilities.

- a. Written procedures have been established for the following quality duties:
  1. Approving/rejecting processes, specifications, procedures, controls, tests, results and deviations
  2. Approving documentation for supplier qualification
  3. Approving documentation for ensuring dietary supplements meet identity, strength, purity and composition specification
  4. Approving test results
  5. Oversight of sampling and retain programs
  6. Determining if specifications are met
  7. Reviewing and approving documentation, documentation practices and revisions
  8. Managing and reviewing change to documents, equipment, facilities
  9. Performing audits and implementing corrective actions
10. Ensuring procedures are followed and the most current revisions are in place
11. Quality shall maintain a change control program for all changes that occur. Document changes shall be controlled and reviewed.
12. Documented training shall occur on all changes.
13. Quality shall approve all corrective actions relating to quality and ensure implementation.
14. Quality shall determine and approve appropriate documentation practices. All procedures and forms shall be dated; revision controlled and signed off by appropriate management. Records and procedures shall be reviewed for compliance at least annually. Appropriate documentation practices include use of ink, no use of whiteout, single line through mistakes initials and date, an X or / through forms or notebooks that aren't used etc. Obsolete or out of date forms or procedures shall not be used.

**Question 101 111.110**

*Quality Control Laboratory Operations have been established.*

- a. Quality reviews and approves test methods and results
- b. Quality releases or rejects product based on compliance to established specifications
- c. Quality has established processes and procedures for laboratory operations including sample handling, results reporting, release/rejection procedures, reference standard programs and OOS result investigations.

**Question 102 111.113a**

*Quality Control Operations and responsibilities have included the authority to reject any component or product if any specification is not met.*

- a. Written procedures establish that quality has the authority and responsibility to conduct material reviews and make product disposition decisions.
- b. Quality must conduct a material review and make a disposition decision if:
  1. Specifications are not met
  2. A batch deviates from the MMR
  3. There is an unexpected occurrence that could lead to adulteration or mislabeling
  4. Calibration or failure of an instrument occurs that could effect batch quality
  5. A dietary supplement is returned

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 103 111.113b**

*Quality Control Personnel may authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.*

- a. Quality must approve all reprocess or rework procedures prior to implementation. Quality must approve all reprocessed or reworked product prior to release.

**Question 104 111.113c**

*The Quality Control person responsible for making the material review and disposition decision has documented the review and disposition decision at the time of performance.*

**Question 105 111.120**

*Quality Control Operations must review and approve components, labels and packaging materials for intended use.*

- a. Review of all receiving records for components, packaging and labeling materials.
- b. Determination that these materials conform to specifications
- c. Approve any component, packaging, and label before it is used in production
- d. Review of testing results, documentation and visual examinations to ensure that all specifications have been met

**Question 106 CFR 111.123a**

*Quality Control Operations and authority have been established for manufacturing records.*

- a. Quality must review and approve all Master Manufacturing Records and any changes.
- b. Quality must issue all batch production records.
- c. Quality shall review and approve all completed batch records prior to product use or release.

**Question 107 CFR 111.123a**

*Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.*

- a. A written procedure shall be established and followed outlining the criteria for releasing product. Quality shall have final authority on releasing product.

**Question 108 CFR 111.1b**

*Quality Control has not approved and released product in any form that does not meet the specifications unless Quality Control approved deviations have been documented.*

- a. Goods may be released on a quality-approved deviation if that deviation will not effect the product's identity, label claim or composition. Examples of quality-approved defects may include changes to packaging approved by the customer. All deviations must be supported with documentation including customer approvals.

**Question 109 CFR 111.130**

*Quality Control Operations have been established to handle returned dietary supplements.*

- a. Return procedures must be established and approved by quality. Quality must approve final disposition decisions relating to returns (salvage, redistribution, reprocessing etc.).

**Question 110 CFR 111.140**

*Quality Control Operations are documented and meet all requirements.*

- a. Written procedures for the responsibilities of the QC unit are established and followed.

**Question 111 CFR 111.140**

*The QC Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained.*

- a. Internal GMP audits shall be conducted annually covering all aspects of the quality control program. This includes but is not limited to sanitation, facilities, pest control, housekeeping, cleaning, batch records, product manufacturing and packaging, preventative maintenance and calibration programs, chemical use programs, standard operating procedures and forms, deviation system, complaint system and laboratory and testing records. The audit should cover among other things, the effectiveness of policies, the applicability of procedures and the completeness of corrective action implementation.
- b. Management shall review internal audits and corrective action with follow up completion shall be documented.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART G 111.153 – 111.180: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR COMPONENTS, PACKAGING, AND LABELS AND FOR PRODUCT  
THAT YOU RECEIVE FOR PACKAGING AND LABELING AS A DIETARY SUPPLEMENT**

**Question 112 CFR 111.153**

*Receiving, sampling, testing, release procedures have been established to fulfill this Subpart.*

- a. Procedures must exist and be current for receipt of all components (raw materials, excipients, bulk goods to be packaged, packaging materials).
- b. Procedures must exist and be current for sampling, testing and release of these components.

**Question 113 CFR 111.155**

*Quality Control requirements have been established for components.*

- a. Controls of components have been established which include visual examination, review of paperwork, sampling of each unique lot, quality testing and review, and quarantine and release.
- b. All components are lot tracked to ensure traceability throughout the supply chain. Controls manage product carryover.
- c. Materials are segregated, status controlled and held to prevent contamination.
- d. Transportation inspections are conducted and storage conditions are appropriate for the component. Components are controlled during transport (tamper evident seals). Components are not subject to adverse conditions during transport or storage.
- e. All product contact components shall have unique lot numbers. If the same lot number could be used by multiple suppliers, unique lot numbers must be assigned upon receipt.

**Question 114 CFR 111.160**

*Quality Control requirements have been established for packaging materials and labels.*

- a. Controls of packaging and labels have been established which include visual examination, review of paperwork, sampling of each unique lot, quality testing and review, and quarantine and release. Controls should include defect action levels for large bulk shipments.
- b. All components are lot tracked to ensure traceability throughout the supply chain. Controls manage product carryover.
- c. Materials are segregated, status controlled and held to prevent contamination or mix-up. Labels of different strength, count are held separately and controlled.
- d. Transportation inspections are conducted and storage conditions are appropriate.
- e. Label controls include methods for checking label copy against formula. Label controls extend to labels printed in house, labels printed externally and labels (or label copy) provided by customers.

**Question 115 CFR 111.165**

*Quality Control requirements have been established for products that are received for packaging and labeling as a dietary supplement and bulk finished product.*

- a. Controls of bulk goods have been established which include visual examination, review of paperwork, sampling of each unique lot, quality testing and review, and quarantine and release.
- b. All goods are lot tracked to ensure traceability throughout the supply chain. Controls manage product carryover.
- c. Materials are segregated, status controlled and held to prevent contamination.
- d. Transportation inspections are conducted and storage conditions are appropriate for the component.

**Question 116 CFR 111.170**

*Rejected components, packaging, labeling, and products are appropriately quarantined and dispositioned.*

- a. Rejects are identified, segregated, status controlled and held to prevent contamination.

**Question 117 CFR 111.180**

*Records have been established and are being maintained to meet the requirements of Subpart G.*

- a. Records are completed timely and by the person performing the work.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART H 111.205-111.210: PRODUCTION AND PROCESS CONTROL SYSTEM:**  
**REQUIREMENTS FOR THE MASTER MANUFACTURING RECORD**

**Question 118 CFR 111.205**

*Master Manufacturing Records have been prepared for each unique formulation and batch size of the dietary supplement.*

- a. Procedures have been established for creation, change, approval and control of MMRs.

**Question 119 CFR 111.205b1**

*The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement.*

- a. MMR's must include all processing steps from production through packaging and labeling.

**Question 120 CFR 111.210**

*Master Manufacturing Records contain all of the required elements.*

- a. Required parts of the MMR:
  1. Name of the dietary supplement to be manufactured
  2. Strength, concentration, weight, or measure of each dietary ingredient for each batch size. All batches must be formulated to 100% of label claim.
  3. A complete list of all components
  4. An accurate statement of the weight or measure of each component
  5. The identity and weight or measure of each dietary ingredient that will be declared on the supplemental facts label and identity of each ingredient that will be declared on the ingredients list
  6. A statement of any intentional overage amount of a dietary ingredient
  7. A statement of theoretical yield at each stage where control is needed to ensure quality
  8. The expected yield after finishing manufacturing, including the allowable variances beyond which an investigation is required
  9. A description of packaging and a representative label (or a cross-reference to the physical location of the actual or representative label)
  10. Written instructions, including specifications at each control point
  11. Sampling procedures and a cross-reference to tests or examinations
  12. Specific actions to perform and verify critical control steps (places for initials/signatures on each critical step for the performer and verifier)
  13. Any special notations or precautions and corrective actions if specifications are not met
  14. References to appropriate SOPs, specifications, etc. if needed
  15. Appropriate review and approval signatures

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART I 111.255 – 111.260: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR THE BATCH PRODUCTION RECORD**

**Question 121 CFR 111.255a,d**

*Batch Production Records are available per Subpart P for each batch of dietary supplement that has been manufactured.*

- a. Procedures have been established for creation, change, approval and control of BPRs.
- b. Procedures have been established for review of the completed BPR's by the relevant technical area and the quality unit.

**Question 122 CFR 111.255b**

*The Batch Record contains complete information relating to the production of each batch.*

- a. Good documentation procedures have been established and are being followed.

**Question 123 CFR 111.255c**

*The Batch Record follows the master record and each step is performed appropriately.*

- a. Required parts of batch records:
  1. The batch, lot, or control number(s) that ensure traceability
  2. Identification of equipment and process lines that were used in the production
  3. If not recorded in log books, then date and time of cleaning, sanitizing and maintenance operations
  4. The lot number of each component, packaging, and label used
  5. Identity and weight or measure of each component used
  6. A statement of actual yield and a statement of theoretical yield at the appropriate stages (if yield is out of allowable variances then investigation and results)
  7. Actual results of any monitoring operations
  8. Results of any in process testing or examinations (or cross-references to the results)
  9. The date and initials of each person performing and verifying steps (weighing and addition steps need verification)
  10. Documentation of packaging and labeling operations at time of performance including the unique identifier for packaging and labels used, label reconciliation, and investigation into reconciliation variances
  11. Actual or representative label of all labels used
  12. The results of finished bulk and/or finished packaged tests or examinations (or cross reference to the results) or documentation that the finished product meets specification if testing is not performed. At minimum quality examinations of finished bulk or packaged product is required.
  13. Quality review of the Batch Record documented at the time of performance
  14. Quality review of all monitoring operations, test results and examinations (components, in-process materials, finished dietary supplement, and packaged and labeled dietary supplements)
  15. Quality Control approval or rejection of any reprocessing or repackaging
  16. Documentation of any material reviews and disposition decisions
  17. Quality Control approval or rejection of the batch

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART J 111.303 – 111.325: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR LABORATORY OPERATIONS**

**Question 124 CFR 111.303**

*Procedures have been established for laboratory operations.*

- a. Procedures have been established and are being followed for laboratory operations including sample handling, results reporting, release/rejection procedures, reference standard programs and OOS result investigations. Skip lot programs if used are established.
- b. Procedures have been established for the operation, maintenance, calibration, and where necessary, cleaning of laboratory equipment.
- c. Procedures have been established for creating specifications.
- d. Test methods have been established.

**Question 125 CFR 111.310**

*Laboratory facilities used are adequate for testing of components, in-process materials, and dietary supplements.*

- a. Contract laboratories shall provide documented results including actual results, methods used, reference standards used if applicable, names and dates.
- b. In house lab facilities are clean and orderly. In full operation, there should be no overlap of testing procedures occurring at the same time.
- c. Equipment (instruments, water systems, etc.) have unique identification, are adequate for intended use and calibration and maintenance is up to date.
- d. Areas for storing reference standards, supplies and reagents are adequately controlled and segregated. In some cases, humidity, temperature, light or other environmental factors may need to be controlled.
- e. Calibration standards, such as standard weight sets for analytical balances, are properly maintained.

**Question 126 CFR 111.310**

*Laboratory controls have been established and have been approved by Quality Control.*

- a. Procedures and methods are up to date and have been reviewed and approved by quality

**Question 127 CFR 111.315**

*Parameters have been set for laboratory controls for sampling plans, criteria for examination and testing methods, etc.*

- a. Criteria exist for establishing specifications, test methods and reference standards.
- b. At minimum, specifications for components and products should include physical, chemical and microbiological aspects.
- c. Sampling plans are written (including skip lot programs), are statistically significant and gather representative samples.
- d. Composite sampling should be taken from a statistical representation of the square root of  $n + 2$ , using an approved technique that removes the sample from the center of the container (sample thief).
- e. Lab notebooks/data files are maintained detailing the methods used, observations, measurements and calculations. All records are dated and initialed by the analyst.
- f. Data review is completed by qualified individuals.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 128 CFR 111.320**

*Quality Control responsibilities for laboratory test methods and examinations used to test each specification requirement have been defined and are being followed.*

- a. Test methods shall exist and be current following good documentation practices for all laboratory methods used. Methods must be an accurate representation of the actual test performed. Methods should reference source, reference standards and reagents used. Methods based on accepted standards (USP, AOAC, BAM) are recommended. Validated procedures shall include quality control measures and the procedures must be followed during analysis. USP criteria for validation are acceptable.
- b. Laboratories should participate in a check sample program with another laboratory to verify reliability and accuracy.
- c. Personnel conducting the testing and examination have documented at the time of performance the laboratory methods that were used. All test results are documented.
- d. Finished product assays must be completed on the finished product form of the product (capsule, tablet, etc).
- e. Weight variation of solid dosage forms and net liquid weight of liquid dosage forms shall be controlled. Tolerance limits shall be established. Corrective actions shall be made on trends and major deviations from control limits. Control charts may be used.
- f. Final products shall meet at a minimum the USP monograph for solid dosage forms where applicable (this includes disintegration requirements).
- g. All finished product shall be tested for microbiological contamination (at a minimum TPC, Y&M, Pathogens (salmonella, e. coli, and staph). Micro testing can occur prior to packaging if an adequate micro and chemical monitoring program are established. The monitoring program shall verify effectiveness of cleaning procedures and shall establish the micro contamination from people and air is controlled.
- h. Skip lot testing for micro would be acceptable if proper testing is in place for raw materials and substantiating documentation is available to support skip lot testing. Positive controls must be in place when conducting micro testing.
- i. All finished product shall be tested to assure the product meets identity, purity, strength and composition specifications (i.e. label claim). A documented system must be in place. One of the following three options is acceptable:
  1. Testing of all ingredients of the finished product to ensure that label claim is met;
  2. Testing all raw materials for potency, formulating to 100% of label claim based on test results and validating the blending process. If blending process can be shown to be similar or the same for multiple products then a generalized blending validation is acceptable, or;
  3. Testing all raw materials for potency and testing finished product for potency (at least one micro and one macro ingredient) to ensure uniformity. Rotation of the micro and macro tested ingredient is required.
  4. Batches or ingredients that test positive for micro contamination (pathogens) shall not be reprocessed or released.
  5. Please reference tables 5A, 5B, 6A, 6B in NSF/ANSI 173 Dietary Supplements for acceptable micro limits.

**Question 129 CFR 111.325**

*Quality Control Operations have maintained appropriate records as required*

- a. Raw data is controlled. Note: The Firm should have established a definition of raw data in writing. There are different forms of raw data depending upon the test, instrument, etc. Electronic raw data must be carefully defined and controlled (see 21 CFR Part 11).
- b. Notebooks, worksheets, electronic records etc. are controlled to assure that there is no loss or destruction of data either by accident or intention.
- c. Inventory records are kept and controlled (e.g. stability inventory, reference standards, etc.).
- d. Written records of all test results, data and calculations shall be kept.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 130 CFR 111.70**

*For all products that bear expiration date or a statement of product shelf life, the shelf life must be supported.*

- a. Stability data is required if products bear an expiration date or best by date. Expiration dates and best by dates are not required
- b. Procedures shall be established for stability testing program if applicable. Program may include accelerated or real time studies.
- c. Stability program shall include establishing stability scheduling, maintenance of the chambers, monitoring of the chambers, handling excursions, inventory accountability, etc. The following are guidelines for an acceptable stability testing program:
  1. 3 batches of a product using the same formulation should be selected for stability testing.
  2. Stability testing should include testing of ingredients that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy. The testing should cover the physical, chemical, biological, and microbiological attributes, preservative content, and functionality testis. These tests should be conducted using fully validated analytical procedures. The date and time of maintenance. Cleaning, and sanitizing of the equipment and processing lines used in producing the batch [or a cross-reference to the documents]
  3. The unique identifier assigned to each component, packaging, and label used
  4. Testing should be conducted on the product in the packaging system proposed for marketing.
  5. For long term studies: Initial testing and then testing every 3 months over the first year, and every 6 months over the section year, and annually thereafter through the proposed shelf life. (So it would be 0, 3, 6, 9, 12, 18, 21, 33, 45, etc.)
  6. For accelerated stability studies (kept in accelerated storage conditions- increased temperature and humidity), a minimum of 3 times points, including the initial and final time points.
- d. Stability chambers provide a controlled environment.
- e. Stability chambers physical inventory matches inventory records to assure accountability of materials. Note: The Firm should perform inventory verification on stability materials at an established frequency (typically 1x per year).
- f. Initial shelf life may be determined by accelerated stability studies or data from similar product formulations. Product shelf life may be confirmed and extended on the basis of real-time stability studies on product stored under labeled storage conditions.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART K 111.353 – 111.365: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR MANUFACTURING OPERATIONS**

**Question 131 CFR 111.353**

*Procedures, including sanitation, operation and control have been established for manufacturing operations.*

- a. Procedures include allowable hold times for equipment after sanitizing is completed.

**Question 132 CFR 111.355**

*Manufacturing processes have been designed to produce a product that consistently meets specifications.*

- a. Manufacturing design must ensure product quality as specified in the MMR.

**Question 133 CFR 111.360**

*Manufacturing Operations are conducted using adequate sanitation principles.*

- a. Manufacturing areas are clean and sanitary. Procedures exist for cleaning process areas as well as equipment.

**Question 134 CFR 111.365a-g**

*Precautions have been taken to prevent contamination, such as micro, filth, chemical, foreign material, etc., throughout the manufacturing process.*

- a. If glass packaging or glass items such as raw material containers, lab glassware or glass monitoring devices are used in production areas, a written glass policy is needed. The written policy shall be current and describe the methods for preventing glass from contaminating product.
- b. Raw agricultural products (roots, leaves, stems/natural form) containing soil shall be washed or screened prior to use.
- c. Effective and documented measures shall be taken to minimize the potential risk of major food allergen cross-contamination in the receipt, storage, production, and shipping of ingredients and finished goods. A documented allergen control program should require the following for allergenic ingredients and allergen-containing finished products at a minimum:
  1. Proper identification of these materials as allergens
  2. Proper storage in designated areas. This means isolation from non-allergenic products and individual allergen segregation.
  3. Use of dedicated manufacturing equipment. If this is not possible, implementation of a validated cleaning procedure that ensures effective removal of the allergen.
  4. Use of dedicated utensils. If dedicated utensils are not used, you must have a validated cleaning program
  5. Effective label control to ensure declaration of allergens
  6. Training of employees
  7. Micro growth is controlled using temperature, water activity, pH or other means.
  8. Storage conditions and locations are appropriate for preventing contamination. Liquids are stored at ground level.
  9. Dietary supplements that can support rapid growth of microorganisms are held in a manner that prevents contamination. Quarantine locations are used.

**Question 135 CFR 111.365h,i**

*Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection.*

- a. Appropriate controls (timers, pH probes, thermocouples etc.) are in place to ensure product quality as specified in the MMR. Blenders have timers.
- b. All products shall be protected from metal and extraneous material inclusion. Metal detection or metal magnets are acceptable for powders. Filters or traps are acceptable for liquids. Magnets shall be cleaned and inspected prior to use. Metal detectors shall be calibrated for the product and its orientation prior to use. Metal detectors shall have documented challenges performed prior to startup.

**Question 136 CFR 111.365j,k**

*Manufacturing operations have included the identification of all process lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number, and when necessary, the phase of manufacturing.*

- a. Containers, piping, rooms, equipment are all identified as to their contents and when necessary process stage or status.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART L 111.403 – 111.425: PRODUCTION AND PROCESS CONTROL SYSTEM:  
REQUIREMENTS FOR PACKAGING AND LABELING OPERATIONS**

**Question 137 CFR 111.403**

*Procedures have been established for all packaging and labeling operations.*

- a. Procedures exist for packaging and label receipt, storage, issuance and reconciliation.
- b. Methods for controlling label revision and changes have been established. Labels should bear a revision code.
- c. A procedure must be established outlining how products are brought to market for any in house produced formulations/products. The procedure should include establishment of marketing claims, development of labels and revision and regulatory review of labels.
- d. If company has own product line, studies, information and data must be kept supporting any marketing statements.

**Question 138 CFR 111.410b**

*Packaging and labels are controlled for issuance and are reconciled after use.*

*Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations.*

- a. Labels shall be stored in a controlled access area. Label receipt procedures shall include a method for determining label changes and/or revision. In the case that the size of the label does not allow for them to be stored in the controlled access area, procedures must be in place.
- b. Quality operations shall issue or review all labels used in packaging.
- c. Reconciliation procedures should include acceptance limits beyond which an investigation is required.

**Question 139 CFR 111.410c**

*Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record.*

- a. Label content must match the formulation used to produce the batch.
- b. Packaging materials must meet specifications.

**Question 140 CFR 111.410d**

*Records are maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution.*

**Question 141 CFR 111.415**

*A Master Manufacturing Record has instructions for filling, assembling, packaging, labeling, and other related operations.*

- a. Packaging and label specifications are included in the MMR.

**Question 142 CFR 111.415a**

*Procedures have been established for cleaning and sanitizing all filling and packaging equipment and utensils.*

- a. Packaging operations should include a pre-startup inspection or line clearance by quality.
- b. All product contact surfaces must have a sanitation step in the cleaning procedure.

**Question 143 CFR 111.415d**

*Physical separation is implemented to prevent mix-ups with other components and dietary supplements.*

- a. If multiple packaging lines exist in the same area, then barriers, signage or other methods are used to prevent mix-ups of components or product.
- b. Appropriate line clearances occur between runs.
- c. Packaging materials present in the location of the packaging line shall be for the current operation only.
- d. Packaging lines are clearly marked as to status.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 144 CFR 111.415**

*Filling and packaging operations are appropriately protected from contamination sources.*

- a. Appropriate covers or other guards are in place on all exposed product.
- b. If packaging materials, such as films, are left on machinery and can become contaminated during downtime, then documented run out of the contaminated material is required.

**Question 145 CFR 111.415e**

*Procedures have been established to identify unlabeled materials that will be held for future labeling operations.*

- a. All containers, boxes or bins must be marked as to the contents.

**Question 146 CFR 111.415f**

*Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement.*

- a. Inspection of the final product and/or its packaging shall be documented to show that correct lot number and expiration dating (if applicable) was used.

**Question 147 CFR 111.415g**

*Procedures have been established to sample a representative number of units to assure compliance with specifications.*

**Question 148 CFR 111.415h**

*Disposal procedures have been established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used.*

- a. Destruction of labels is documented in writing.
- b. Labels containing obsolete lot identification information shall be destroyed.

**Question 149 CFR 111.420a**

*All repackaging or relabeling operations have first been approved by the Quality Control Unit.*

- a. Procedures have been established for repacking and re-labeling. Procedures ensure lot traceability throughout the operation.

**Question 150 CFR 111.420b**

*Representative samples of each batch of repackaged or relabeled dietary supplement have been examined to determine if they conform to specifications.*

**Question 151 CFR 111.420c**

*Quality Control Unit has dispositioned each batch of repackaged or relabeled dietary supplement prior to release for distribution.*

**Question 152 CFR 111.425**

*An appropriate quarantine system has been established for holding any rejected packaged and labeled dietary supplement.*

**Question 153 CFR 111.425**

*Storage areas have been demonstrated to meet the necessary requirements.*

- a. Labels shall be stored separated by strength, product quantity and product type.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART M 111.453 – 111.475: HOLDING AND DISTRIBUTING**

**Question 154 CFR 111.455**

*Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration.*

- a. Procedures for storage are based on label recommendations.

**Question 155 CFR 111.460**

*In-process materials requiring specific holding conditions (temperature, humidity etc.) are stored appropriately.*

- a. If required, storage conditions must be documented and have action limits beyond which corrective actions are needed.

**Question 156 CFR 111.470**

*Distribution of product must occur under conditions that will protect against contamination and deterioration.*

- a. Documented inspection of transport vehicles is required.
- b. Product must be sealed with tamper evident seals and shipped in containers that protect against physical, chemical or microbial contamination or deterioration.

**Question 157 CFR 111.475b1**

*Procedures have been established for the holding and distribution operations.*

- a. Shipping procedures cover shipping product in quarantine if needed. Generally, shipping procedures cover movement of product after quality release. Procedures must delineate how this hand off occurs between the two departments. Computer controls are adequate.

**Question 158 CFR 111.475b2**

*Product distribution records have been retained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.*

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART N 111.503 – 111.535: RETURN OF DIETARY SUPPLEMENTS**

**Question 159 CFR 111.503**

*Procedures have been established for the handling of returned dietary supplements.*

- a. Procedures shall be established for the receipt, handling, examining and testing requirements for all returned material.
- b. Records must include reason and date of return and ultimate disposition of the product. Returns for any quality reason or because of a customer complaint shall be reviewed by quality and investigated if appropriate.
- c. Procedures shall be established outlining requirements for disposition (salvage, recovery) decisions. Quality must approve all dispositions.
- d. Procedures shall be established for the methods of destroying or otherwise disposing of any product. Disposal must be documented.

**Question 160 CFR 111.510**

*Returned supplements have been appropriately quarantined until dispositioned by the Quality Control Unit.*

**Question 161 CFR 111.515**

*Any returned dietary supplement must be either destroyed or disposed of unless the Quality Control Unit has determined that the material can be salvaged or reprocessed.*

- a. Product that does not meet specifications, is returned unsealed or has been subject to improper storage conditions shall be destroyed.

**Question 162 CFR 111.520**

*Any salvaged material has been so designated by the Quality Control Unit.*

**Question 163 CFR 111.525**

*Any reprocessed material has met its original specification and the Quality Control Unit has appropriately dispositioned the material (release or reject).*

**Question 164 CFR 111.530**

*If the reason for a return implicates other batches, an investigation has been performed to determine if those batches comply with specifications.*

**Question 165 CFR 111.535**

*Procedures have been established for salvage and reprocessing operations according to Subpart P.*

**Question 166 CFR 111.535b**

*Documentation has been maintained for material reviews and dispositions, all testing results, any reevaluations by the Quality Control Unit for reprocessed materials.*

- a. Batch record documentation shall be kept for all reprocessed returned material ensuring lot traceability of finished goods and components.

**Question 167 CFR 111.535b4**

*All Quality Control Unit evaluations and decisions have been documented.*

- a. Material review records include investigations and conclusions. Corrective actions have been documented and implemented when necessary.

**Question 168 CFR 111.535**

*Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.*

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART O 111.553 – 111.570: PRODUCT COMPLAINTS**

**Question 169 CFR 111.553**

*Procedures have been established describing how product complaints will be received, investigated, and documented.*

- a. Written complaint procedures are in place and being used. All relevant personnel have been trained.
- b. A method to link the complaint to returns or recalls exists.

**Question 170 CFR 111.560a**

*All product complaints have been reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality.*

- a. All complaints shall be reviewed by quality.

**Question 171 CFR 111.560b**

*The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.*

- a. Where adequate information exists complaints should be investigated. The investigation should result in root cause analysis of the complaint. Corrective actions should be implemented and documented.

**Question 172 CFR 111.560c**

*The investigation for a product complaint was appropriately extended to other batches, products, processes, etc.*

**Question 173 CFR 111.570a**

*Records for each product complaint and investigation have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.*

**Question 174 CFR 111.570bii**

*Product complaint information has included adequate information.*

- a. Complaint information includes the following:
  1. Name and description of the dietary supplement
  2. Batch, lot, or control number (if available)
  3. The date of the complaint and the name, address, and telephone number of the complainant (If available)
  4. The nature of the complaint and how the product was used
  5. Any reply to the complainant
  6. Findings of the investigation and any follow-up actions

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**SUBPART P 111.605 – 111.610: RECORDS AND RECORDKEEPING**

**Question 175 CFR 111.605**

*Procedures have been established that describe the requirements for record retention under Subpart P.*

- a. A written records retention procedure shall exist and include definitions of original records and copies. Records to be kept include receipt, batch and process control, testing and laboratory, maintenance and calibration, distribution, complaints and investigations, returns, rework, reprocessing, and cleaning and sanitation.
- b. Record recovery procedures should be established as a part of a disaster recovery plan.
- c. Record destruction should be documented.

**Question 176 CFR 111.605**

*Records will be maintained for 1 year after the shelf life date or 2 years beyond the date of distribution of the last batch associated with those records.*

**Question 177 CFR 111.605**

*All records are maintained as original record, as true copies or as electronic records.*

**11.10 – 11.50: ELECTRONIC RECORDS**

**Question 178 CFR 11.10**

*Procedures and controls have been established for electronic closed systems used to create, modify, maintain, or transmit electronic records in order to ensure the authenticity, integrity, and confidentiality of the records [Closed Systems].*

- a. Procedures must be established for closed system (access restricted) electronic systems.
- b. Qualified individuals are responsible for developing, maintaining, or using the electronic records. Training and job descriptions are complete.

**Question 179 CFR 11.10**

*The procedures and controls include adequate information.*

- a. Closed system controls and procedures shall include the following elements:
  1. Validation procedures
  2. Protection from unauthorized access and methods for removing users from the system
  3. Date and time stamps must be independently created
  4. Operational, authority and device checks completed periodically
  5. Written policies to deter falsification
  6. Training
  7. Distribution, revision and change controls
  8. Procedures include definition of critical electronic data and information that would be defined under GMP usage. Typically, administrative and financial systems are specifically excluded.
  9. Procedures for data integrity verification.
  10. Procedures for the control of electronic data including adequacy of electronic media, back-up, security and access, audit trail functions, permission levels, archival and storage, retrieval, etc.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 180 CFR 11.30**

*Procedures and controls have been established for use of open electronic systems. Areas of control have been identified, as necessary, per the requirements in 11.10.*

- a. Qualified individuals are responsible for developing, maintaining, or using the electronic records. Training and job descriptions are complete.
- b. Procedures must be established for open systems and include the following elements.
  1. Date and time stamps must be independently created
  2. Operational, authority and device checks completed periodically
  3. Written policies to deter falsification
  4. Training
  5. Distribution, revision and change controls
  6. Procedures include definition of critical electronic data and information that would be defined under GMP usage. Typically, administrative and financial systems are specifically excluded.
  7. Procedures for data integrity verification.
  8. Procedures for the control of electronic data including adequacy of electronic media, back-up, security and access, audit trail functions, permission levels, archival and storage, retrieval, etc.

**Question 181 CFR 11.50**

*Electronic signatures conform to requirements.*

- a. Electronic signatures have to be part of any version of the document including screen views etc.
- b. Electronic signatures must include printed name, date and time of signature and the meaning of the signature (approval, reviewer etc.)

**Question 182 11.70**

*Electronic and hand-written signatures have been linked to the electronic record.*

- a. Hand-written signatures to electronic record and any electronic signatures to electronic records must be linked to the records to prevent copying or transference of any signatures falsely.

**Question 183 11.100- 11.200**

*Electronic signatures meet requirements.*

- a. Electronic signatures must be unique to a previously identified individual and are legally binding.
- b. Signatures must be controlled by an ID code and password (unless biometric controls are used) and used only by their genuine owners.

**Question 184 11.300**

*Passwords and codes have been established.*

- a. Passwords and ID codes must be unique and revised periodically.
- b. Procedures must be established for loss management.
- c. Safeguards must be in place to prevent unauthorized usage.
- d. If cards or tokens are used to generate passwords or ID codes, then these devices must be tested.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**NSF/ANSI 173 Section 8.1: Recall Procedures**

**Question 185 NSF 8.1**

*Procedures have been established to define the recall of a product.*

- a. Written recall procedures shall exist and be current.
  1. Mock recall needs to be conducted annually to challenge the procedures and traceability system.
  2. Recall procedures should cover finished product recalls and recalls from component, raw material vendors.
  3. Recall procedures shall outline the three classes of recalls outlined by the FDA.
  4. Recall procedures shall identify members of the recall team, responsibilities (including public relations) and contact information (including FDA/regulatory contact information).

**NSF/ANSI 173 Section 8.2: Compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

**Question 186 NSF 8.2**

*Manufacturers of dietary supplements shall submit application to USFDA for registration, receive a registration number, and provide the registration number upon request.*

- a. Facility and any sub facility that manufactures, processes, packs or holds a dietary supplement has a Bioterrorism registry number.
- b. Goods not in the firm's direct control are sealed to prevent tampering. This includes receipts as well as shipments.

**NSF/ANSI 173 Section 8.3: Adverse Event Reporting**

**Question 187 NSF 8.3**

*Procedures shall be established and followed for reporting serious adverse events to the USFDA in accordance with the dietary supplement and non-prescription drug consumer protection act.*

- a. A procedure has been established for recording any adverse events received by the company and reporting any serious adverse events to the FDA.
- b. All adverse event reports and records must be kept for 6 years.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Appendix 1**  
**NSF 229 – Functional Food Guideline, Section 7**  
**Preliminary – Administration & Regulatory Compliance**

**Question 188 NSF 7.1**

*Personnel supervisors are laid out in an organizational chart.*

- a. There shall be a plant management organization chart that shows the reporting structure of the plant operating departments, as well as the reporting relationship of the Quality Manager both internally and to a corporate or head office if applicable. The document must be current, dated and signed by the appropriate responsible executive. Further, there should be an organizational chart showing the structure of the Quality organization.
- b. The Quality Manager must be responsible to local plant manager (not production manager) or to a designated corporate official to assure that quality and product safety decisions can be made independently. Consideration will be given to small and very small plants where individuals have numerous organizational responsibilities.

**Question 189 NSF 7.1**

*Policies and procedures have been established addressing product safety and quality that are relevant to the receiving, handling, manufacturing, shipping, control and evaluation of food/dietary supplement products.*

- a. The documentation should clearly define expectations through detailed product and process specifications, testing procedures, sampling programs and acceptance/rejection criteria. These documents must be well organized, current, dated, signed by management and readily available. Policies and procedures shall be reviewed and should be revised if necessary on an annual basis. Changes should be clearly identified and appropriately signed and dated.

**Question 190 NSF 7.1**

*Regulatory actions, visits and reports have been documented and are kept on file.*

- a. Records of all regulatory actions, visits, reports or other notifications received from any regulatory agency shall be maintained. Written responses with appropriate corrective actions must be documented for every written inspection, audit or other official notification from any regulatory agency.

**Question 191 NSF 7.1**

*A procedure shall be available that specifies the development and management of policies and procedures. A policy must also specify requirements for the management of completed process and process-related records.*

- a. A master list of documents should be maintained.
- b. Documents should be reviewed for adequacy on a scheduled basis, and revised if necessary.
- c. Changes to documents should be properly approved.
- d. The current revision status of all documents must be available to avoid use of invalid or obsolete documents.
- e. Obsolete documents must be clearly identified and maintained for historical purposes.
- f. All records relevant to the control of the process or evaluation of product safety, quality and security will be:
  1. Recorded on a timely basis with the applicable date and time.
  2. Recorded in ink, not pencil, with any errors crossed out with a single line and initialed.
  3. Complete with no missing data.
  4. Initialed by the operator and verified by the supervisor.
  5. Indexed and easily retrievable.
- g. A records retention policy shall specify the retention period, storage conditions, and proper disposition following the retention period for each type of record.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**HACCP Management**

**Question 192 NSF 7.2**

*A HACCP program has been established.*

- a. A formal Hazard Analysis and Critical Control Point (HACCP) plan must be in place for each product or product family to analyze and control potential biological, chemical and physical hazards from receipt of raw materials, through production, packaging and shipping of finished products.
- b. The HACCP plan must be approved by top management. The plan must also be maintained current with regular (at least annual) assessments conducted by the HACCP management team that document performance and/or changes needed in the Plan. Annual assessments must be reviewed and signed by top management. If at any time a process, formula, ingredient, equipment or facility change is made, the HACCP team must immediately and formally evaluate the change to determine if the HACCP Plan is impacted, making all necessary changes to the plan documents.

**Question 193 NSF 7.2**

*HACCP plans have been documented.*

**Question 194 NSF 7.2**

*Hazard analyses have been established for each type of product or product line.*

**Question 195 NSF 7.2**

*Procedures have been established to determine whether a step or process is a control point or a critical control point.*

- a. Logical reasoning approach should be used to determine Critical Control Points (CCPs) for hazards.
- b. Training in the application of the decision tree is recommended.
- c. Documentation for determining whether a step or process is a CCP or not must be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), "Decision Tree" or the CODEX decision tree should be applied in determination of CCPs.
- d. NOTE: If it has been determined that there are no hazards or CCPs, no further HACCP plan development is necessary. However, the HACCP Team must continue to conduct regular meetings to review any changes in the process or procedures that would affect the hazard or CCP determination.

**Question 196 NSF 7.2**

*Operating and critical limits have been established.*

- a. Critical limits must be specified and validated for each CCP.
- b. Critical limits must be measurable.
- c. There must be a scientific or regulatory basis, with appropriate documentation or regulatory references, to both the hazard and the control required. Proprietary data may be acceptable, providing there is sufficient data that is approved by an appropriate, qualified process authority.
- d. Process Capabilities must be documented to demonstrate that established CCP limits are compatible with the plant process and capable of being met.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 197 NSF 7.2**

*Monitoring procedures have been established to detect loss of control at the CCP.*

- a. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control.
- b. Monitoring data must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.
- c. Documentation of the measured variable must be on clearly identified HACCP Records. Records must have CCPs identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance.
- d. A deviation log must be maintained and available for review.
- e. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company. Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.

**Question 198 NSF 7.2**

*Corrective actions have been established for each CCP in the HACCP system in order to deal with deviations when they occur.*

- a. Corrective actions must include instructions of necessary actions to take to secure and manage affected product.
- b. Corrective actions must ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.
- c. Product disposition procedures that would become effective if a deviation were to occur must be developed.

**Question 199 NSF 7.2**

*HACCP procedures have been documented.*

- a. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.
  1. Examples of documentation include Hazard analysis; CCP determination; Critical limit determination.
  2. Examples of Record Keeping include CCP monitoring activities; Deviations and associated corrective actions; Verification procedures performed; Modifications to the HACCP plan.
- b. Deviations from the HACCP plan must be thoroughly documented with detailed corrective actions and product dispositions.
- c. The documents and their data must be self-explanatory and complete. The records must be in ink (not pencil) and signed by the operator. There must be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation must be provided.
- d. The final record must be signed by the operator, the supervisor and by the designated HACCP records reviewer.
- e. Records must be easily retrievable and secured in a safe storage area.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Allergen Control**

**Question 200 NSF 7.3**

*Allergenic ingredients are clearly identified.*

**Question 201 NSF 7.3**

*Allergenic ingredients are segregated in storage from non-allergenic ingredients.*

**Question 202 NSF 7.3**

*The risk of cross-contamination has been minimized.*

- a. Where dedicated equipment is not available, production scheduling should require production of allergen-containing products at the end of the day.
- b. Cleaning methods for process equipment and utensils should be validated to ensure complete removal of all allergenic ingredients.
- c. Dedicated utensils (preferably color-coated) should be used with different allergens.

**Question 203 NSF 7.3**

*Products containing allergens have been labeled to meet federal regulations.*

- a. Per requirements of the Food Allergen Labeling and Consumer Protection Act of 2004, finished product labels must clearly identify any ingredients that contain protein derived from the eight major allergenic foods.

**Question 204 NSF 7.3**

*Allergen training is conducted as part of the GMP training program for all employees.*

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Appendix 2**  
**NSF – 306 GMP for Sport**

**Sourcing and Traceability**

**Question 188 NSF 306**

*Production facility must maintain supplier approval process for products.*

**Question 189 NSF 306**

*Products shall be traceable through all stages of production, transportation, storage, processing, and manufacturing.*

**Question 190 NSF 306**

*Traceability documentation shall be established and followed.*

**Question 191 NSF 306**

*Facility shall have signed copy of the manufacturing affidavit.*

**Question 192 NSF 306**

*If applicable, facility shall maintain signed ingredient supplier affidavits for products manufactured for the NSF Athletic Banned Substances Program.*

**Customer Service, Inventory Management, Order Fulfillment**

**Question 193 NSF 306**

*Procedures for customer service, inventory management, and order fulfillment shall be established and followed.*

**Laboratory Operations**

**Question 194 NSF 306**

*If facility is currently outsourcing to other laboratories, please provide documentation detailing the laboratories used and specifically the work being done.*

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Appendix 3**  
**NSF – 306 GMP for Sport &**  
**NSF 229 – Functional Food Guideline, Section 7**

**Sourcing and Traceability**

**Question 188 NSF 306**

*Production facility must maintain supplier approval process for products.*

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**Laboratory Operations**

**Question 194 NSF 306**

*If facility is currently outsourcing to other laboratories, please provide documentation detailing the laboratories used and specifically the work being done.*

**Preliminary – Administration & Regulatory Compliance**

**Question 195 NSF 7.1**

*Personnel supervisors are laid out in an organizational chart.*

- a. There shall be a plant management organization chart that shows the reporting structure of the plant operating departments, as well as the reporting relationship of the Quality Manager both internally and to a corporate or head office if applicable. The document must be current, dated and signed by the appropriate responsible executive. Further, there should be an organizational chart showing the structure of the Quality organization.
- b. The Quality Manager must be responsible to local plant manager (not production manager) or to a designated corporate official to assure that quality and product safety decisions can be made independently. Consideration will be given to small and very small plants where individuals have numerous organizational responsibilities.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Question 196 NSF 7.1**

*Policies and procedures have been established addressing product safety and quality that are relevant to the receiving, handling, manufacturing, shipping, control and evaluation of food/dietary supplement products.*

- a. The documentation should clearly define expectations through detailed product and process specifications, testing procedures, sampling programs and acceptance/rejection criteria. These documents must be well organized, current, dated, signed by management and readily available. Policies and procedures shall be reviewed and should be revised if necessary on an annual basis. Changes should be clearly identified and appropriately signed and dated.

**Question 197 NSF 7.1**

*Regulatory actions, visits and reports have been documented and are kept on file.*

- a. Records of all regulatory actions, visits, reports or other notifications received from any regulatory agency shall be maintained. Written responses with appropriate corrective actions must be documented for every written inspection, audit or other official notification from any regulatory agency.

**Question 198 NSF 7.1**

*A procedure shall be available that specifies the development and management of policies and procedures. A policy must also specify requirements for the management of completed process and process-related records.*

- a. A master list of documents should be maintained.
- b. Documents should be reviewed for adequacy on a scheduled basis, and revised if necessary.
- c. Changes to documents should be properly approved.
- d. The current revision status of all documents must be available to avoid use of invalid or obsolete documents.
- e. Obsolete documents must be clearly identified and maintained for historical purposes.
- f. All records relevant to the control of the process or evaluation of product safety, quality and security will be:
  1. Recorded on a timely basis with the applicable date and time.
  2. Recorded in ink, not pencil, with any errors crossed out with a single line and initialed.
  3. Complete with no missing data.
  4. Initialed by the operator and verified by the supervisor.
  5. Indexed and easily retrievable.
- g. A records retention policy shall specify the retention period, storage conditions, and proper disposition following the retention period for each type of record.

**NSF GMP GUIDANCE DOCUMENT**  
**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

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**21CFR § 11/111**  
**NSF/ANSI 173 Section 8**

**Allergen Control**

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**Question 208 NSF 7.3**

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**Question 211 NSF 7.3**

*Allergen training is conducted as part of the GMP training program for all employees.*