Quality Assurance Guidelines—A New Necessity

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ABSTRACT

More and more of the governments of developing countries are promulgating regulations which deal with food safety. Of necessity, these regulations must be general in nature to cover all food industries in a particular country. Legislation either exists or is pending in many of these countries to require individual plants or companies to have a written document stating the steps which are being taken in their plants to assure food safety. The United States has already issued regulations or Good Manufacturing Practices for Human Foods which resulted in the Salt Institute *Quality Assurance Guidelines Manual* developed by the members of the Salt Institute for the Salt Industry. Only individual companies can prepare rules for the specific type of food grade salt operations in which they are engaged. The document, therefore, merely gives guidelines to serve as a model for salt producers. The considerations made in developing these guidelines, such as the control points in a typical evaporating plant and the associated hazards of adulteration, are generally applicable to all salt plants and are the subject of this paper.

INTRODUCTION

More and more of the governments of the developed countries are promulgating regulations which deal with food safety. The United States has already issued regulations or Good Manufacturing Practices for Human Foods and the Salt Institute has developed a *Quality Assurance Guidelines Manual* for the Salt Industry.

WHAT IS QUALITY ASSURANCE?

Quality Assurance is the design, management, and monitoring of an organized system of controls over those critical points in a production line that affect, either beneficially or adversely, the compliance of a finished product with certain desirable characteristics. When properly implemented, quality assurance systems provide assurance that the end product meets desired characteristics with a given consistency. This assurance is qualifiable in probabilistic terms, and the application of statistical principles provides the basis for this measurement.[1] It is the intent of the Salt Institute Quality Assurance Guidelines Manual to assure consumers that they are receiving a safe, wholesome, and nutritious product from the Salt Industry as well as a uniform product.

FOOD PROCESSOR'S QUALITY ASSURANCE SYSTEM

In the Food Industry in general, food processors should try to guard against microorganisms (including molds and mycotoxins), heavy metals, naturally occurring toxins, industrial chemicals, pesticides, nutritional loss, etc. They should attempt to maintain basic good sanitary practices. They should also be aware of regulatory requirements and guard against fraudulent practices, improper labeling, and improper additives. They should also be conscious of economic waste such as over-fill, line waste, high spoilage, or the use of unnecessary ingredients.[1]

THE DIFFERENCE BETWEEN QUALITY ASSURANCE AND QUALITY CONTROL

Top management approves basic policies. These are expressed as goals and objectives. Quality Assurance has to then express these goals and objectives in their area of responsibility as standards. Quality Control then takes these standards and performs inspections to make sure that all production meets the standards. Once the standards are issued, Quality Assurance periodically monitors Quality

Control to make sure that Quality Control is performing its function.

For example, top management may decide that 100-pound bags should be filled to the average weight printed on the bag which implies that 1–2% of the bags will be under net weight. Quality Assurance then interprets this to mean that the set point is 100 pounds, 6 ounces. On the other hand, top management may decide that they do not want any underweight bags under any and all circumstances. Quality Assurance then interprets this to mean that the set point should be 101 pounds.

Once the set point is decided upon, it is the responsibility of Quality Control to inspect bags on a regular basis to assure that there are no more than 1–2% underweight bags in the first case or no underweight bags in the second. In either case, there should be no excessively overweight bags. Quality Assurance should periodically monitor Quality Control to make sure that they are following inspection procedures and reporting any deviation from the standards.

HEALTH HAZARDS AND SANITATION

The United States has already issued regulations for Good Manufacturing Practices for food plants.[2] These Practices concern sanitation and should be considered prior to Hazard Analysis and Critical Control Point analysis. Good Manufacturing Practices concern the plant and grounds, equipment and utensils, sanitary facilities and controls, sanitary operations, and personnel. For example, the grounds about the plant should be free from improperly stored equipment, litter, waste, refuse, and uncut weeds or grass; excessively dusty roads, yards, or parking lots; and inadequately drained areas that may contribute to foot board filth or provide a breeding place for insects or microorganisms. Floors, walls, and ceilings should be clean and in good repair.

Equipment and utensils should be designed so that they are adequately cleanable. Their design, construction, and use should preclude the contamination of salt with lubricants, metal fragments, contaminated water, or other contaminants. New equipment should be designed and installed so as to facilitate adequate cleaning of the equipment and the surrounding area.

An adequate supply of potable water at a suitable temperature and pressure should be available. The plant should provide its employees with adequate toilet and associated hand washing facilities and these facilities should be maintained in a sanitary condition and kept in good repair. Doors to the toilet room should be self-closing and steps should be taken to prevent air flow from entering process areas. Toilets should be conveniently located and signs posted directing the employees to wash their hands with soap after using the toilet. A sanitary towel service should be provided along with waste receptacles that are easily cleanable. Rubbish should be disposed of in a manner that will minimize the development of odor and in such a way as to eliminate contamination of salt, salt contact surfaces, ground surfaces, and water supplies.

Pest and rodent control should be done by a licensed control service or licensed or trained employee with a written report issued. A map should be prepared of bait stations and/or traps in and outside the plant and rat traps should be chained down. Only rodenticides and insecticides approved by the controlling authority should be used. Monthly reports should be submitted and maintained at the manufacturing site for at least 2 years. Windows and other openings in the plant which do not require access or egress should be screened to keep the plant free of insects, rodents, and birds.

Persons infected with a communicable disease, boils, or sores should be prevented from working in a capacity whereby they can contaminate the product. Clean, suitable, and tight garments should be worn by employees working in direct contact with salt preparation, salt ingredients, or salt contact surfaces. Employees working in direct contact with salt preparation, salt ingredients, or salt contact surfaces should be required to wear effective hair restraints. Employees should not be allowed to smoke, drink, or store personal belongings in areas where they are in direct contact with salt preparation, salt ingredients, or salt contact surfaces.

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

The control points in a typical evaporating plant and the associated hazards of adulteration are discussed in this section. Figure 1 shows that the first process is the water source. The water should be potable water, free from heavy metals, bacteria, and maintained in a sterile condition with chlorinating facilities. The first critical point is between the Water Treatment and Water source. All Water Treatment additives must meet FDA or other applicable specifications. They should be inspected and segregated upon receipt.

Figure 1 also shows the second critical point which is between Brine Treatment and Treatment. Additives for Brine Treatment should be inspected for code dates, vendor guarantees, and should be periodically analyzed. The third critical point is between the Feed Brine in Figure 1 and the Evaporators in Figure 2. This critical point should be visually examined to make sure that magnets and filters are in place, that the covers over tanks and conveyor belts are intact, and that the brine in the brine tanks appears to be in satisfactory condition. The brine should also be analyzed for insolubles.

The next critical point is between the Additives, such as crystal modifiers, additives for pH control, and foam depressants, and the Evaporators. Generally, these additives are

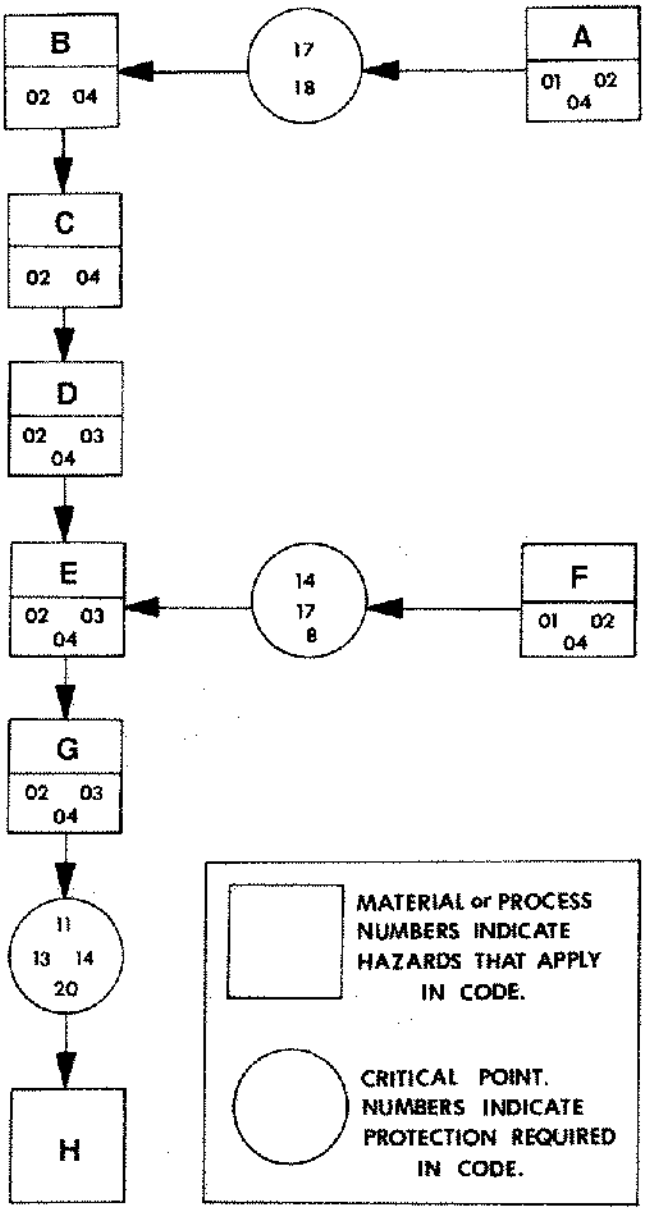

Figure 1. Brine flow. a) Water treatment—additives. b) Water source. c) Salt source—deposits—dissolvers—slurries. d) "Raw brine". e) Treatment—degassify, pH—precipitation—settling, filtration—miscellaneous. f) Brine treatment—additives. g) "Feed brine". h) Evaporation.

accepted on vendor guarantees, once a vendor has been established based on previous performance.

The next critical point is shown on Figure 2 between Water and the water which goes to Salt-Brine Separation and the Evaporators. Again, all of the additives which are used in water treatment should meet FDA specifications and the water should be potable. Furthermore, filters should be intact and the Top Feed Filter should be inspected to insure that no contamination can enter at this point. A second critical point in this area is between the Air and the Salt-Brine Separation. The filter in this air which is used for drying should be inspected to be sure that it is intact. The brine from the Top Feed Filter should also be examined prior to returning it to the Evaporators.

Figure 3 contains one critical point between Air, Heat and Moisture Removal. The filter at this point should be checked to make sure that it is intact and keeping the air clean. Another critical point is between Moisture Removal and Screening. This point should be visually inspected to make sure that this screen is intact and not overloaded, and a sample should be submitted to the laboratory on a regular basis for analysis.

Another critical point on Figure 3 is between Additives (Non-caking) and either before or after Screening. Vendor guarantees are usually relied upon for additive and chemical specifications. The final critical point after screening is examined in the laboratory to insure that the product is what the customer wants and/or what the producer desires.

In Figure 4, the product is segregated according to whether it is to contain Additives or No Additives. The salt operation containing no additives is merely inspected to make sure that the conveyors are properly covered and samples are taken to make sure that the salt meets the desired physical and chemical specifications. All additives added to the salt at the Mixing (Batch, Continuous) must be given a screen analysis, check weight, the code date and vendor guarantees examined, and any recall procedures instituted which result from this inspection. The section of the plant containing salt mixed with additives is then inspected to make sure that conveyor covers are in place.

Salt with or without additives can be packaged in 26-ounce, 3-pound, 5-pound or 10-pound containers; 25, 40, 50, 80 and 100-pound bags, drums, and tote bins; compressed blocks, bricks, briquettes, and compacted tablets; and bulk loaded into box and hopper cars. Critical Points prior to any of these operations should be checked to make sure that magnets are in place, the scalping screens are intact and performing their proper function, and that conveyor covers are in place. Each container of salt should be checked after packaging to make sure that it has the proper weight or volume; meets chemical and physical specifications; and contains no extraneous materials. The examination of the packaged material is primarily made to determine any contamination which has entered the salt through packaging. This includes inspecting the bags themselves. For example, the paper in the bag can contain polychlorinated biphenyls or paper lice.

RECALL PROCEDURE

Suppose that the worst happens? Suppose that it is found after your product has reached distribution channels that an incorrect additive has been included? The answer is that you

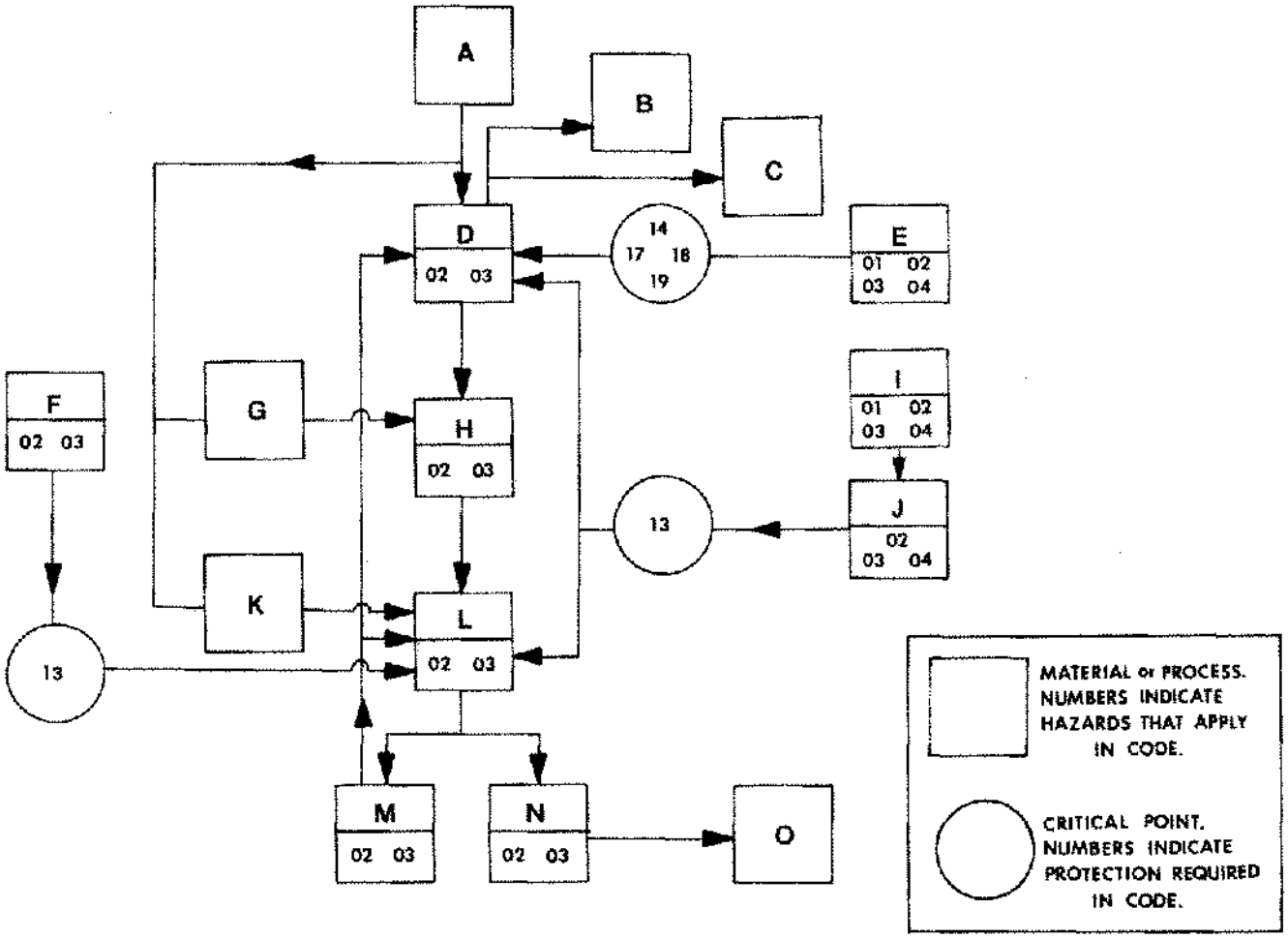

Figure 2. Evaporation flow. a) Brine flow. b) Steam—condense, recompress. c) Purge—waste, recycle, reprocess. d) Evaporators—effects, pans, vessels, crystallizers, grainers. e) Additives—crystal modifiers—pH control—foam depressants. f) Air-heated or ambient. g) Elutriate. h) "Salt slurry". i) Additives—water treatment. j) Water—dissolve, salt—wash. k) Wash. l) Salt-brine separation—top feed filter—centrifuge—gravity drainage—rinse, brine removal—partial drying. m) Brine—recycle, n) Salt-varying moisture levels. o) Drying.

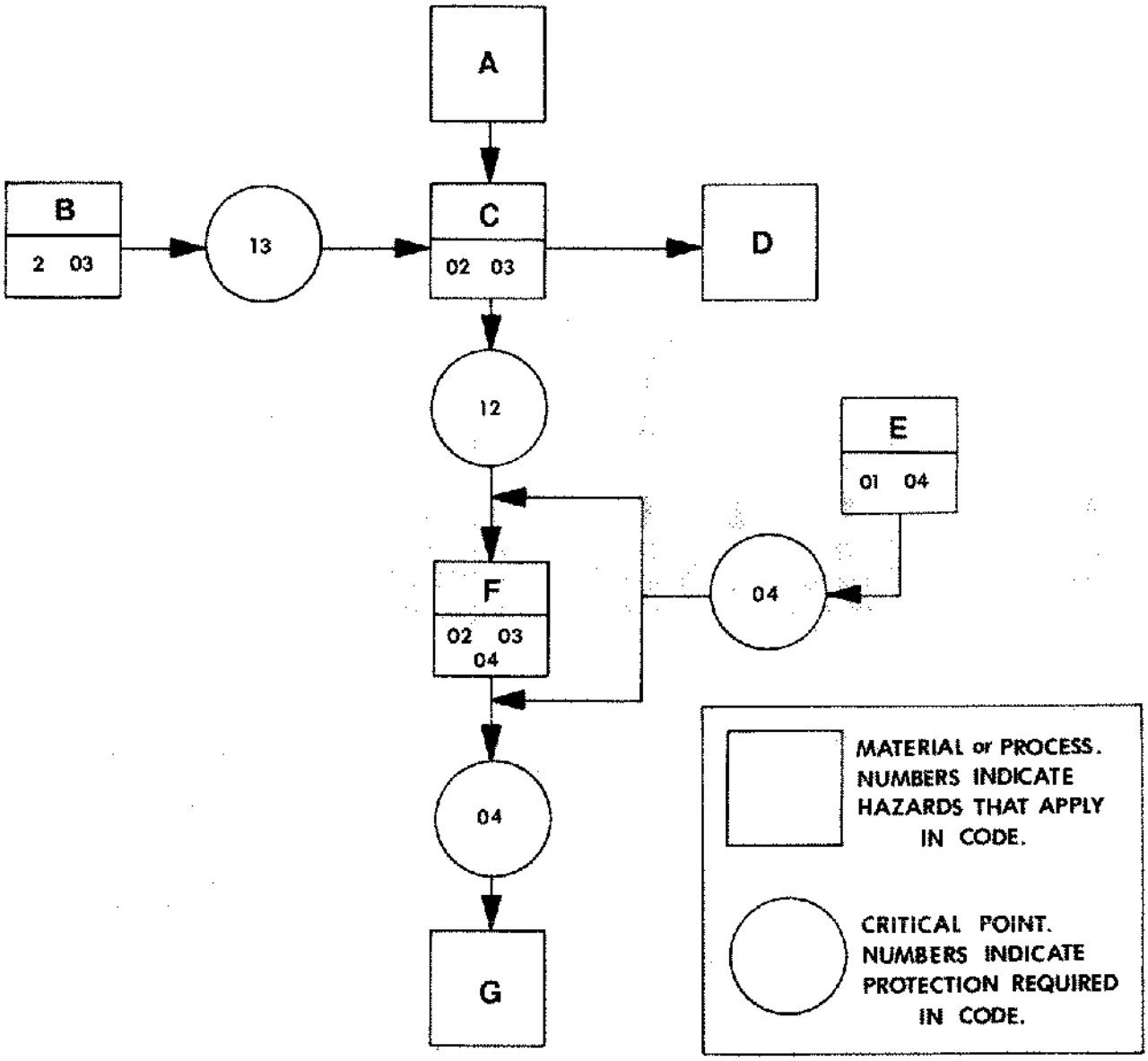

Figure 3. Drying and screening. a) Evaporation. b) Air, heat. c) Moisture removal—drying, cooling. d) Moisture. e) Additives—non-caking. f) Screening—size separation. g) Processing.

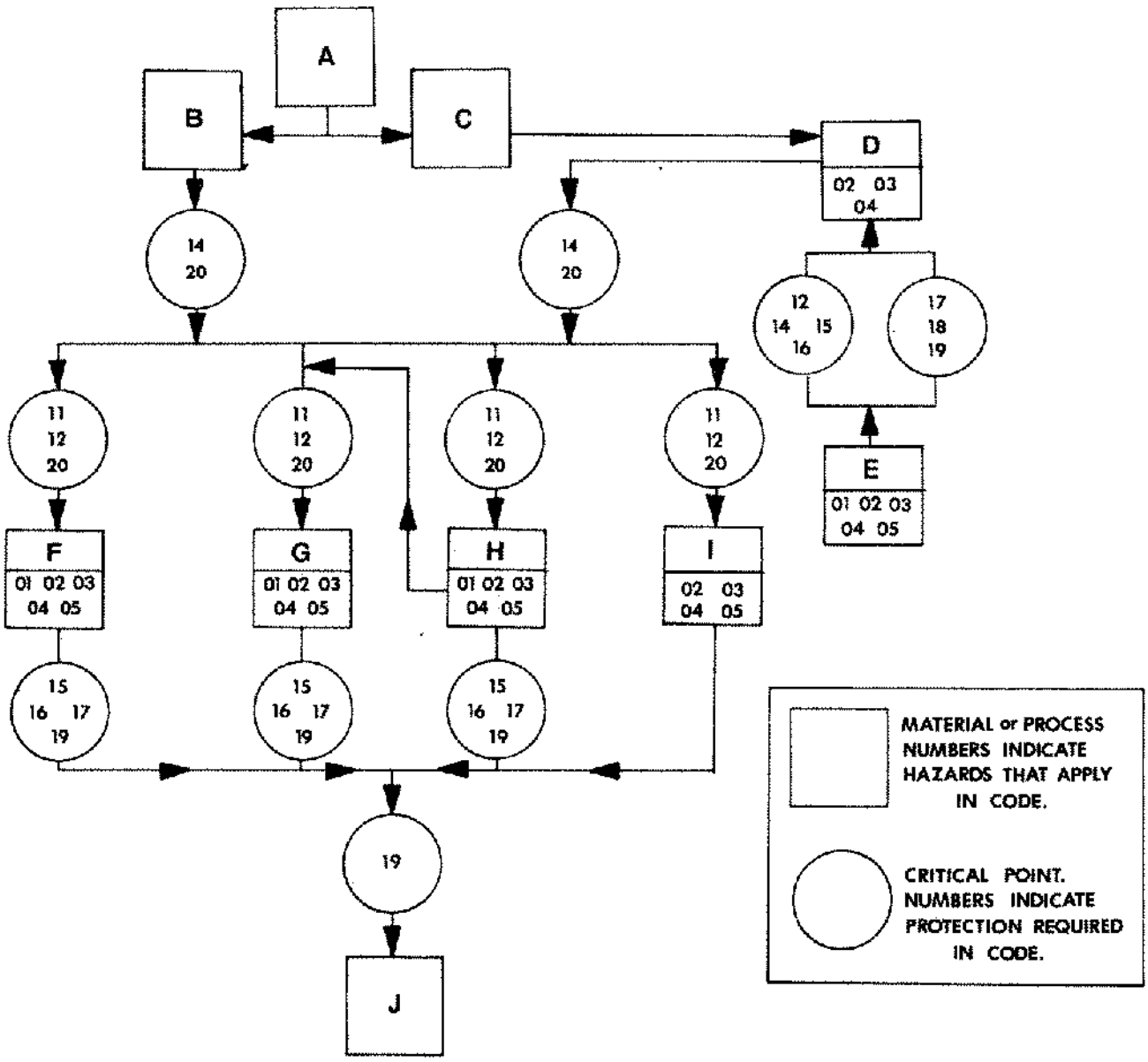

Figure 4. Processing. a) Drying and screening. b) No additives. c) Additives. d) Mixing—batch, continuous. e) Additives—minerals, iodine—anti-caking, drugs—free-flow, miscellaneous. f) Packages—26 oz., 5 lb., 10 lb., individual, 3 lb., miscellaneous. g) Containers—25, 40, 50, 80, 100 lbs—drums, tote bins. h) Compressed—blocks, bricks, briquettes, compacted, tablets. i) Bulk—box hoppers, pneumatic. j) Shipment.

must have a system for retrieving product that is in violation of existing laws or that the manufacturer wishes to reclaim for one reason or another.

A company may learn of the possible need for a recall from a number of sources, such as federal agencies, etc. Early clues may be delayed or lost in shuffling between customer, public health people, and corporate personnel. There is no way to always be able to clearly identify and separate a complaint which may necessitate a product recall from those which do not, when it is received from sources other than the federal government. An organization must exist for analyzing and classifying all product complaints, and if a recall is necessary, a plan of action must be decided upon and federal agencies notified.

A recall strategy or plan of action can be developed by a federal agency and/or the recalling firm to suit the circumstances of the particular recall. The time to plan for recall is well in advance, and the first essential is a fine coding system for products through the manufacturing and distribution processes. To be prepared to handle a recall situation at any time, a standby recall organization should be created within the company structure, so that a recall can be handled expeditiously and thoroughly.

SYSTEM FOR UPDATING

After having written these guidelines for the Salt Industry, do we believe that they all apply and are complete? The answer to the first part of the question is that we do not know whether they all apply. It is the opinion of most people who serve on the Quality Assurance Guidelines Committee of the Salt Institute that it probably will require at least one year's experience to find out whether the Manual can be applied to the Industry or if it must be modified to cover realistic Industry situations.

Furthermore, it would be almost impossible to say that the *Manual* is complete. In order to update the *Manual*, it has been agreed by the Industry to report federal violations to the Institute so that they can be listed on an anonymous company basis and used by the members to modify the *Manual* so that it covers all those violations.

REFERENCES

1. Angellotti, R. FDA's Plan for Quality Assurance in the Food Industry.
2. Code of Federal Regulations, Chapter 1—Food and Drug Administration, Part 128.