

(3) When containers are packed more than 60 to a case but not more than 250, draw a maximum of 16 sample units from any one case; and

(4) When containers are packed more than 250 in a case, draw a maximum of 24 sample units from any one case.

[31 FR 4687, Mar. 19, 1966, as amended at 36 FR 18456, Sept. 15, 1971. Redesignated at 42 FR 32514, June 27, 1977 and 46 FR 63203, Dec. 31, 1981]

§ 42.106 Classifying and recording defects.

(a) *Classifying defects.* Examine each sample unit for the applicable type of defects listed in the table covering the container being inspected in §§ 42.112 and 42.113. Other defects, not specifically listed, shall be classified according to their effect on the intended use of the container.

(1) Related defects are defects on a single container that are related to a single cause. If the initial incident causing one of the defects had not occurred, none of the other related defects on the container would be present. As an example of related defects, a can may be a leaker and the exterior may also be seriously rusted due to the leakage of the contents. In this case, the container is scored only once for these two defects since the rust condition can be attributed to the leak. Score the container according to whichever condition is the most serious. In this example, score as a "leaker" (a critical defect) and not as "pitted rust" (a major defect).

(2) Unrelated defects are defects on a single container that result from separate causes. If the incident that caused one of the defects had not occurred, the other unrelated defects on the container would still be present. As an example of unrelated defects, a can may be seriously rusted, may have a bad dent along the seam, and the label may also be detached from the can because of improper gluing. In this case it is unlikely that any of the three defects exist because of a common cause. Therefore, they are considered unrelated defects and should be scored as three defects.

(3) The lot acceptance portion of this procedure is based on the number of defects per 100 containers. It is necessary

to determine if the defects on any one container are "related" defects or "unrelated" defects. A container is scored for the most serious of related defects, and is also scored for each unrelated defect.

(b) *Recording defects.* Record on a worksheet the number, type, and class (critical, major, or minor) of defects on each sample unit.

(c) *Totaling defects.* Add the number of defects in each class, then add the number of minor, major, and critical defects to obtain the total defects.

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§ 42.107 Lot acceptance criteria.

(a) The acceptability of the lot is determined by relating the number and class of defects enumerated on the worksheet to the acceptance and rejection numbers shown in §§ 42.109 through 42.111 for the respective sample size and Acceptable Quality Level (AQL).

(b) Unless otherwise specified, use the following AQL's for the respective class of defects:

| Defect class | AQL at origin inspection | AQL at other than origin inspection |
|----------------|--------------------------|-------------------------------------|
| Critical | 0.25 | 0.25 |
| Major | 1.5 | 2.5 |
| Total | 6.5 | 10.0 |

(c) Refer to the appropriate sample size and AQL and compare the number of defects found in the sample with the acceptance (Ac) and rejection (Re) numbers in the sampling plan.

(1) Accept the lot after examining the single sample or first sample of a double sampling plan when all of the following conditions are met:

(i) The number of critical defects does not exceed the applicable acceptance number (Ac) for critical defects, and

(ii) The number of major defects does not exceed the applicable acceptance number (Ac) for major defects, and

(iii) The total number of critical, major, and minor defects does not exceed the applicable acceptance number (Ac) for total defects.

(2) Reject the lot after examining the single sample or first sample of a double sampling plan when any one or more of the following conditions occur:

- (i) The number of critical defects equals or exceeds the applicable rejection number (Re) for critical defects, or
- (ii) The number of major defects equals or exceeds the applicable rejection number (Re) for major defects, or
- (iii) The total number of critical, major, and minor defects equals or exceeds the applicable rejection number (Re) for total defects.

(3) If the lot can neither be accepted nor rejected on the first sample, when a double sampling plan is used, select and examine the prescribed second sample. Accept the lot if the accumulated defects of the first and second sample meet conditions of paragraph (c)(1) of this section, otherwise, reject the lot.

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§ 42.108 Normal, tightened, or reduced inspection.

(a) *Normal inspection.* Sampling plans for normal inspection are those in Tables I and I-A. These plans shall be used except when the history of inspection permits reduced inspection or requires tightened inspection.

(b) *Tightened inspection.* Sampling plans for tightened inspection are those in Tables II and II-A.

(c) *Reduced inspection.* Sampling plans for reduced inspection are those in Tables III and III-A.

(d) *Switching rules.* The normal inspection procedure shall be followed except when conditions in paragraph (d) (1) or (3) of this section are applicable or unless otherwise specified. Application of the following switching rules will be restricted to the inspection of lots for one applicant at a single location (plant, warehouse, etc.), and will be based upon records of original inspections of lots (excluding resubmitted lots) at that same location.

(1) *Normal inspection to reduced inspection.* When normal inspection is in effect, reduced inspection shall be instituted providing that reduced inspection is considered desirable by the Ad-

ministrator and further provided that all of the following conditions are satisfied for each class of defect:

(i) The preceding 10 inspection lots (or more, as indicated by the note to Table III-B) which have been inspected within the preceding 6 months have been on normal inspection and none has been rejected on original inspection; and

(ii) The total number of defects in the samples from the preceding 10 inspection lots (or such other number of lots used for condition in paragraph (d)(1)(i) of this section) is equal to or less than the applicable number given in Table III-B. If a double sampling plan is used, all samples inspected should be included, not "first" samples only; and

(2) *Reduced inspection to normal inspection.* When reduced inspection is in effect, normal inspection shall be re-instituted if any of the following occur:

(i) An inspection lot is rejected on original inspection; or

(ii) Production becomes irregular (delayed or accelerated); or

(iii) Other valid conditions warrant that normal inspection shall be re-instituted.

(3) *Normal inspection to tightened inspection.* When normal inspection is in effect, tightened inspection shall be instituted when 2 out of 5 consecutive inspection lots have been rejected on original inspection.

(4) *Tightened inspection to normal inspection.* When tightened inspection is in effect, normal inspection shall be re-instituted when five consecutive inspection lots have been considered acceptable on original inspection.

(e) When the rules require a switch in the inspection status because of one or more classes of defects, all classes of defects shall be inspected under the new inspection criteria. At the option of the user of the service and when approved by the Administrator, such user may elect to remain on normal inspection when qualified for reduced inspection, or on tightened inspection when qualified for normal inspection.

(f) *Appeal inspection*—(1) *Appeal request.* Any interested party who is not satisfied with the results of a condition