

**Conference for Food Protection
2010 Issue Form**

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Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Title:

Change in Program Standard No. 6 and Appendix F, Compliance and Enforcement

Issue you would like the Conference to consider:

Currently for a jurisdiction to meet Standard No. 6, under Description of Requirement, 3., the program element needed is "documentation on the establishment inspection report form or in the establishment file showing compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out of control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F." As more and more jurisdictions work toward meeting Standard No. 6, it has become apparent that the current sample size needs to be increased so that the probability of a jurisdiction passing and meeting the Standard accurately reflects the conditions experienced by enrolled jurisdictions. Based on an improved analysis of the requirements for a jurisdiction to pass, it is recommended that the minimum number of establishments chosen for file review be changed from 20 to 40 with the maximum number remaining at 70.

In addition the following phrase within the language of Requirement 3 needs clarification, "achieve compliance at least 80 percent of the time". The language change should be ". . . where at least 80 percent of sampled establishments . . ." (See the recommended solution below for full text changes). The change in wording clarifies the requirements for meeting the Standard.

Public Health Significance:

The number of establishments (file records) used in the calculation of the scoring affects the probability of a jurisdiction passing with a score of 80%. The recommendation is to increase the sample size in the Standard to improve the probability of a high-performing jurisdiction passing the Standard and to clarify the language to avoid confusion in the calculation of the scoring (or rating) of files as pass/fail.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the modified language proposed be incorporated into Standard 6 and Appendix F, Supplement to Standard 6 - Compliance and Enforcement of the Voluntary National Retail Food Regulatory Program Standards.

Modify Standard 6 so that it reads:

Description of Requirement

" . . . The essential program elements required to meet this standard are:

1. No Change.
2. No Change.
3. Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, where at least 80 percent of sampled establishments meet the following conditions:

a) The inspection and enforcement staff takes compliance and enforcement action according to the procedures (i.e., the staff follows the step-by-step compliance and enforcement procedures when violations occur), and

b) Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.

~~3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80-percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.~~

- ~~1. Compliance and enforcement actions that follow the step-by-step procedure.~~

Documentation

" The quality records needed for this standard include:

1. No change.
2. No change.
3. Documentation that compliance and enforcement action was taken correctly for at least 80% of sampled establishments ~~80-percent of the time~~ using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. No change.

Modify Appendix F, Supplement to Standard 6 - Compliance and Enforcement so that it reads:

Selecting the Sample

Jurisdictions with under 800 total establishments will select 40 files for review, or if they have less than 40 establishments in the inventory, then all files are to be reviewed.

Jurisdictions with 800 or more establishments will select a sample equal to 5% of the total establishments up to a maximum of 70 files. This initial selection of sample files will be the initial sample and will be the first files reviewed. Sample selection using a table of random numbers or a random number generator is the preferred method of sample selection and can be used with a card file, ledger, list, or automated data system. However, two alternative sample selection techniques acceptable for retail food program self-assessments are presented here.

1. Method 1. No change.

2. Method 2. The second alternative technique to the use of a random number generator utilizes a card file, ledger, list or data processing record system. When this procedure is used, all the establishments in the program must be subject to sampling. The frequency interval may be determined by dividing the total number of retail food establishments by the number of files needed in the sample. (For example, if there are 800 establishments within

the jurisdiction, a sample of 40 would be needed (5% of ~~80~~ 800). The frequency interval would be 800 divided by 40, or 20. Thus every 20th establishment shall be selected to make up the initial sample.) To establish a starting point when using a frequency interval of 20, write numbers 1 - 20, inclusive, on separate strips of paper and draw one slip at random. The number appearing on that strip of paper represents the first establishment to be drawn. If a ledger or list is being used for sampling and the number drawn is 7, then the seventh entry in the ledger or list would be the first establishment in the sample. The second establishment would be the 27th entry, the third would be the 47th entry and so forth, until the sample of 40 is drawn.

Alternate Sample List

Paragraphs 1 -4: No Change.

Paragraph 5, Change to read:

If method 1 is used for the random selection, the alternate sample files will be the last files drawn. For example, if the sample size required is 40, then 52 files will be selected, and the last 12 files drawn will be designated as alternative files.

Paragraph 6 to end of Appendix F - No Change.

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Attachments:

- "Attachment A - Standard 6-Compliance and Enforcement"
- "Attachment B-APPENDIX F Supplement to Standard No. 6"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.