

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 308, 317, 318, 319 and 381

[Docket No. 95-032F]

RIN 0583-AB93

Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations by removing the requirements for prior approval by FSIS of establishment drawings, specifications, and equipment used in official establishments. Requirements involving the comparison of blueprints and specifications with actual facilities and equipment will end, affording industry the flexibility to design facilities and equipment in the manner they deem best to maintain a sanitary environment for food production. FSIS will continue to verify through inspection that sanitation requirements are being met. FSIS is also ending its prior approval of most establishment-operated partial quality control programs, which are used by establishments to control certain kinds of food processing and product characteristics. This change will enable establishments to develop and implement quality control programs without first having to receive permission from FSIS to do so. This action is being taken as part of FSIS's regulatory reform effort to improve FSIS's meat and poultry food safety regulations, better define the roles of Government and the regulated industry, encourage innovations that will improve food safety, and remove unnecessary regulatory burdens on inspected establishments.

DATES: *Effective Date:* September 24, 1997.

Comments: Comments on the guidance material published as Appendices A and B of this document must be received by October 24, 1997.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, DOCKET #95-032F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, 300

Twelfth Street, S.W., Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia F. Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development, and Evaluation, FSIS, Room 402 Annex Building, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION:**Background**

The Federal meat and poultry products inspection regulations currently require establishments applying for inspection to submit to FSIS multiple sets of drawings and specifications of the facilities for approval before inspection can be granted (9 CFR 304.2, 381.19). The regulations require plans to be submitted to the Agency for approval before any remodeling of facilities (9 CFR 308.2, 381.19(e)). The regulations also require approval by FSIS of equipment and utensils proposed for use in preparing edible product or product ingredients in official establishments (9 CFR 308.5, 381.53). Further, the regulations require Agency approval of partial quality control programs before establishments can use them for control of food processing or for other uses (318.4 (d)-(g), 381.145 (d)-(g)).

FSIS proposed in the May 2, 1996, **Federal Register** (61 FR 19578) to amend these regulations to eliminate requirements for FSIS prior approval. The Agency also proposed a minimum standard for the design of PQC programs that is comparable to the standard for programs the Agency has approved. For the reasons given in the preamble to the proposal and in this final rule, FSIS is adopting the proposed amendments with some additional changes occasioned by FSIS's review of the proposed rule and the comments on that proposal.

Comments

FSIS received 27 comments during the public comment period that ended September 9, 1996. Five were from industry consultants, seven from equipment manufacturers and engineering firms, eight from food companies, four from trade associations, one from a law firm representing packers and equipment manufacturers, and two from State departments of agriculture. Twelve commenters expressed qualified support for eliminating prior approval of equipment and facility blueprints, thirteen favored keeping the present approval system, and two suggested alternatives. All 13 comments received on the specific issue

of eliminating PQC prior approvals supported the proposed change.

In addition to the comments submitted on the May 2, 1996, proposal, five comments supporting the elimination of prior approvals were submitted in response to the Agency's December 29, 1995, advance notice of proposed rulemaking "FSIS Agenda for Change: Regulatory Review." Four of the five comments were from persons who also commented on the May 2 proposal.

The following summarizes the comments on the proposal and Agency responses by major topic addressed.

Circuit Supervisor and Inspection Decisions

Most commenters, whether favoring or opposing the proposal, expressed concern that eliminating prior approvals of facilities and equipment would leave establishments without documented approvals with which to counter adverse judgments by circuit supervisors during walkthroughs conducted before the granting of inspection or by field inspectors during daily establishment operations. The commenters feared that conflicts arising over decisions by such Agency personnel could delay production and otherwise burden establishments. Ten commenters opposed the proposal for this reason. Six others, though favoring the proposal, had the same concern and thought the Agency should take steps to prevent or minimize any disruptions arising from decisions made by local Agency personnel.

These commenters tended to assume that FSIS inspection will not change in conjunction with the regulatory reforms now taking place. FSIS disagrees. FSIS inspection roles will change significantly under the recently promulgated final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems" (61 FR 38806; July 23, 1996). Under this rule, FSIS personnel will verify the effectiveness of processes and process controls designed to ensure food safety. FSIS is preparing the inspection workforce to oversee the safety of meat and poultry products under this new HACCP-oriented inspection. FSIS personnel will focus on an establishment's ongoing compliance with HACCP-consistent requirements. Inspectors will carry out verification activities such as reviewing establishment monitoring records for a process, reviewing records for a production lot, directly observing critical control point controls conducted by establishment employees, collecting samples for FSIS laboratory analysis,

and verifying establishment verification activities for a process.

Inspection findings that affect facilities or equipment will be made in the context of such verification activities. Inspectors will retain the authority to reject facilities or equipment wherever appropriate and warranted by the circumstances. Establishments will have the responsibility to take corrective action when they discover process deviations while operating their HACCP systems. Proper design and implementation of sanitation standard operating procedures (SOP's) and the HACCP system will minimize any differences of opinion with Agency personnel that may occur.

Provision of Guidance Material, Transition to HACCP

A number of commenters (8) who favored the proposal thought that the Agency should make guidance materials on facilities and equipment available to inspectors and establishments, especially to small establishments. These commenters stated that the guidance materials, including a revised Agriculture Handbook 570, *U.S. Inspected Meat and Poultry Packing Plants: A Guide to Construction and Layout*, and equipment acceptability standards, would help maintain uniformity and consistency in inspection decisions and would also be of use to small establishments. One commenter thought there should be periodic updates to Handbook 570. Some commenters stressed that the Agency should emphasize to inspectors that the guidance documents are not rules and regulations, but are intended to illustrate basic principles to be applied in a variety of situations.

As explained in the proposal, FSIS is preserving the final edition of Agriculture Handbook 570 and the general guidance material in MPI-2, *Accepted Meat and Poultry Equipment*, for reference. This guidance material is appended to this document as Appendix A. The Agency agrees with the commenters that this guidance material should not be interpreted as a set of regulations, but as a statement of basic principles with illustrative examples. The specific application of these principles will depend, in part, on the establishment's implementation of its sanitation standard operating procedures and its HACCP plan. The Agency also plans to issue a final list of approved equipment, reflecting FSIS decisions through November 1996. Appendix A is a final draft on which the Agency will accept comments for 60 days. Comments on whether the

material is clear and useful will be especially helpful in finalizing the material.

Effect on Small Companies

A few commenters (3) thought that eliminating prior approvals would be harmful to small companies that are unable to hire experts in food processing facilities or equipment to assist them in complying with regulatory requirements.

As explained above, FSIS has prepared technical guidance material on facilities and equipment that should be especially useful to small establishments. The Agency will continue to maintain a small staff of experts at Washington headquarters to monitor developments in food technology and disseminate advice and materials concerning applications of the technology. The Agency also plans to make the technical guidance material it develops available to the public in electronic format.

Prestige of USDA Acceptance

One commenter thought that, with the ending of the FSIS acceptance program for equipment, U.S. manufacturers would suffer a disadvantage in international markets for food processing equipment. The commenter stated that equipment manufacturers were previously able to trade on the value of USDA acceptance of their products for use in federally inspected plants.

Although FSIS appreciates the fact that its decisions on meat and poultry slaughtering and processing equipment are valued, the acceptance program was never intended for equipment market promotion. Its purpose was to help ensure that meat and poultry establishments would operate in a safe, sanitary manner, producing and shipping only wholesome, unadulterated meat and poultry products.

Limited Value of Prior Approval

One commenter agreed and another disagreed with the Agency's contention that an initial determination that meat and poultry facilities and equipment meet Agency requirements is of limited value. Prior approval does not guarantee that establishments will continuously operate facilities and equipment in a safe and sanitary manner. FSIS's position, as previously stated, is that effective sanitation SOP's and HACCP systems will meet the same objectives as prior approvals.

Third-Party Certifications

Several commenters suggested the use of third-party certifications of facilities and equipment. One commenter favoring the proposal suggested that FSIS consider the voluntary use by establishments of third-party assessment and registration programs to ensure the development and implementation of effective sanitation and HACCP programs.

FSIS agrees with the commenter that third-party programs can make a useful contribution to the effort of developing and implementing sanitation SOP's and HACCP plans. The Agency, realizing that some establishments will be unable to avail themselves of these services and that many will not need to, is not requiring the use of such services. Also, the Agency does not intend to formally recognize or accredit such services. However, FSIS agrees that third-party certification services may be advantageous to many establishments and would support an industry initiative in this area. An example of such a third-party certification service is the 3-A Sanitary Standards Committee, which conducts a certification program for equipment used in dairy and egg products processing establishments.

Number of Blueprint Submissions and Evaluation

One commenter disputed the number of blueprint submissions to the Agency during fiscal year 1994 (2,100, versus the Agency's estimate of 2,900) and the Agency's attribution of most rejections to paperwork errors. The commenter asserted that most rejections were attributable to deficiencies that could affect food safety. The commenter also suggested that because the proposal was based, in part, on the Agency's incorrect estimate of the number of blueprints it evaluated and the reasons for returns and rejections of the blueprints, the basis for the proposal was faulty, and that, for this reason, the proposal ought to be withdrawn.

FSIS's estimate of the number of submissions at about 2,900 for fiscal year 1994 was derived from information in a blueprint evaluation database that was intended to show trends in workflow through the Washington review staff rather than absolute numbers of submissions. In fiscal year 1994, the Agency also maintained a separate count of returns of blueprints to their originators. Some blueprint sets go back and forth between the Agency and the originating establishment several times before they are approved. The Agency used a sample of blueprint evaluation records from the database,

adjusted for multiple returns, in estimating the number of submissions it handled.

The commenter's count may have been based, in part, on internal Agency reports. The data in those reports is comparable to the data used by the Agency in arriving at its estimate. FSIS considers the commenter's count as a reasonable lower-bound estimate of the number of submissions and is using it for the purpose of assessing the impact of this rule.

However, FSIS disagrees with the commenter's belief that most blueprint rejections were the result of factors affecting food safety. During periods of high workload, the Agency's Washington staff has tended to return a higher proportion of blueprint sets with administrative errors to the originating establishments and request resubmission. During periods of lower workload, the staff has been able to telephone establishments, offer advice relating to the compatibility of blueprints with guidelines, and receive corrections of administrative errors by fax. The percentage of returns to correct specifications that have implications for food safety was somewhat higher in periods of lower workload than in high-workload periods. Most recently, it has been the policy of the blueprint review staff to focus strictly on regulatory compliance—that is, on checking for specifications required by the regulations—rather than on compatibility with guidelines. As a result, the percentage of blueprint returns attributable to paperwork errors has been higher than in the past.

The estimate of blueprint submissions and rejections was used to conduct a regulatory impact assessment. Moreover, the Agency's estimate of impact is only a part of the basis for the rule. As stated in the preamble to the proposal, there are several other important reasons for the rule. First, it is important to note that the Federal Meat Inspection Act and the Poultry Products Inspection Act do not require prior approval of facilities, equipment, and quality control programs. More importantly, prior approvals are limited in scope because they apply only to certain aspects of establishment operations and in time because they are given only once. The establishment is and has always been responsible for maintaining sanitary facilities and equipment every day it operates. Also, prior approval is a feature of the traditional command-and-control approach to regulation that can be an obstacle and deterrent to innovation. Eliminating prior approvals is consistent with the new regulatory

requirements for establishment-operated sanitation SOP's and HACCP systems, under which the establishments will fulfill their responsibility for determining and implementing process controls that will assure food safety. Under these new requirements, prior approval is an inappropriate allocation of responsibility between the Agency and establishments.

Enforcement, Dispute Resolution, and Appeals

A number of commenters (4) asked what recourse establishments would have if FSIS took action against or refused to allow the use of equipment or facilities that had not previously been approved by FSIS. Commenters asked whether appeal procedures would be provided or whether another form of dispute resolution would be available to establishments if the proposal were adopted.

FSIS understands the concern and is developing procedures for resolving issues such as these which may arise under the HACCP-based inspection system. The Agency emphasizes, however, that under the new program, inspectors will not be evaluating equipment and facilities directly. Rather, inspectors will evaluate the operational effectiveness of facilities and equipment in preventing direct product contamination and other hazards.

FSIS is currently revising its rules of practice and will include procedures for dispute resolution and appeals of FSIS decisions. Until those rules of practice become effective, current enforcement and appeal procedures will continue to be followed.

Partial Quality Control Programs

As mentioned above, 13 comments favored the elimination of prior approval of establishment-operated PQC programs, but most were accompanied by questions and suggestions concerning the Agency's policy on PQC approvals.

Continued Prior Approval of Certain Quality Control Programs

Three commenters asked why the Agency was eliminating prior approval for certain PQC programs, but retaining prior approval requirements for other PQC programs. One commenter noted that the proposal did not address prior approval of Total Quality Control programs.

Although eliminating most prior approvals, FSIS is retaining certain specific regulatory provisions for prior approval of PQC programs. These include programs associated with

certain slaughter inspection systems and with food irradiation facilities. Also, this final rule does not eliminate prior approval of TQC programs. The Agency plans to deal with these issues during the next few months in rulemakings intended to address the remaining prior approval requirements for PQC and TQC.

Specific Requirements for PQC Programs

A number of commenters questioned the requirements that PQC programs would have to continue to meet. Two commenters wondered why the Agency was prescribing design criteria for PQC programs, including the required elements and minimal statistical confidence, when they were eliminating prior approval. Another commenter thought that the National Institute of Standards and Technology (NIST) Handbook 133, concerning net weight, should be amended to eliminate specific references to approved PQC programs.

The PQC program design criteria set forth in the regulations are consistent with those currently observed by the industry. The Agency proposed the requirements, including the 85-percent statistical confidence criterion, to provide the industry with a set of minimum standards for PQC programs. A sampling plan should be consistent with the principles of statistical process control and the proposed requirement included such a plan. Nevertheless, the Agency agrees that a precise sampling plan does not have to be set out in the regulations. The Agency also agrees that the proposed specifications relating to the minimum confidence level, individual sample means, and subplot means are too prescriptive. Accordingly, these specifications are not being adopted in this final rule.

Further, establishments are not required to include all the features presented in proposed §§ 318.4(2)(ii) and 381.145(2)(ii) in its individual PQC programs. The final rule only requires that a PQC program include those elements that are "appropriate for the product, operation, or part of an operation which the program concerns." The final rule also requires that generally recognized statistical process control procedures be used to determine process control. However, the final rule is worded to accommodate control procedures that are not statistically based or that do not have measurable control limits, such as the in-plant control procedures for grade-labeled product.

As to NIST Handbook 133, FSIS does not see a need to amend the Handbook at this time. The Handbook states that

data generated by USDA-approved PQC programs can be used to substantiate lot compliance with net weight requirements. Even without prior approval by FSIS, a PQC program meeting the requirements of this final rule could generate data appropriate for determining product compliance with net weight requirements. Such data will be recognized and checked by FSIS inspection personnel just as data generated by prior-approved PQC programs have been until now.

In order to facilitate establishment development of PQC programs that meet the requirements of this final rule, the Agency has developed guidance material which includes the criteria it used to determine whether or not PQC's were acceptable. The guidance material, which is included as Appendix B, may be used by establishments at their discretion.

Appendix B, as with Appendix A, is a final draft on which the Agency will accept comments for 60 days. Comments on whether the material is clear and useful to establishments will be especially helpful in making final revisions to the Appendix.

Upon publication of this final rule, FSIS will revise Agency directives and other documents referring to PQC's. The category of "conditional" PQC's in these documents will be eliminated and the categories "mandatory" and "voluntary" will remain. The "mandatory" category will be abolished once all regulations requiring Agency-approved PQC's for certain processes have been amended.

Effect of Mandatory HACCP on PQC Programs With Public Health Implications

Two industry commenters wanted to know what effect the HACCP requirements would have on existing and future PQC programs, which include measures relating to public health or safety protection. Although this final rule eliminates the requirement for prior approval of most PQC programs, PQC programs remain an option for controlling certain processes. As HACCP is implemented in an establishment, safety-related PQC programs will most likely be incorporated into the establishment's HACCP plan. As HACCP plans are implemented throughout the meat and poultry industry, public health-related PQC programs will no longer be needed. Establishments will, of course, continue to be able to develop and use PQC programs that control "economic" factors.

A State government suggested that the Agency continue prior approval of such

PQC programs. FSIS disagrees. The Agency's position is that such control programs should be implemented voluntarily, at the establishment's discretion.

Third-Party Certification of PQC Programs

One commenter suggested that FSIS make use of third-party certification services for PQC programs.

As stated above, third-party certification services may be useful and advantageous to many establishments, and FSIS would support industry initiatives in this regard. However, the Agency does not plan to require third-party certification or to officially recognize, accredit, or oversee their operations.

Export Requirements

One commenter noted that some foreign countries require product exported to them from U.S. establishments to have been processed under approved PQC programs, and requested that the foreign requirements be changed to accord with the new U.S. regulations.

However, FSIS has no direct control over the requirements of foreign governments. Establishments must abide by the requirements of the countries to which they export. Since FSIS is no longer approving PQC programs, if a foreign government requires a U.S. establishment to process product exported to that government's territory under an approved PQC program, then the establishment should obtain approval for the program from that government.

The Final Rule

FSIS is adopting the provisions in the proposal in essentially the same form as proposed, but with some technical changes. In §§ 318.4(d) and 381.145(d), concerning PQC programs, the phrase "is required to have" replaces "is using" for greater consistency with the intent to provide flexibility to establishments and reduce regulatory paperwork burdens associated with voluntary PQC's. As mentioned, some of the PQC program design criteria in proposed §§ 318.4(d)(2)(ii) and 381.145(d)(2)(ii) are not being adopted. Also, §§ 318.4(d)(2)(ii) and 381.145(d)(2)(ii) are worded to accommodate procedures that do not have measurable limits, as well as statistically based PQC's.

Additionally, FSIS is making certain technical corrections in this final rule, which are occasioned by FSIS's review of the proposed rule and the comments on that proposal. The wording of amended §§ 317.21, 318.19(e) and

381.121d is changed somewhat from the proposed wording to clarify that certain requirements for quality control will continue even though the prior approval requirements for PQC programs are removed. The proposal did not include proposed amendments eliminating the prior-approval requirement for blueprints of import inspection establishments or of establishments operating under State meat or poultry inspection programs that are "at least equal to" the Federal program. The revised 9 CFR 327.6(d), 331.3 and 381.222 eliminate these prior-approval requirements. States may continue to require establishments to submit blueprints for approval as a condition of receiving inspection, but because FSIS is eliminating its prior approval programs, the Agency will no longer consider prior approval of blueprints to be a necessary feature of an "at least equal" inspection program.

Also, FSIS inadvertently omitted changes, consistent with the intent of this rulemaking, to some sections of the regulations that refer to PQC prior approvals. These sections include 9 CFR 319.105, on the processing of cured ham products and 9 CFR 318.308 and 381.308, on the processing of canned foods. The final rule amends these sections of the regulations to eliminate the references to PQC prior approvals.

Relationship to Sanitation SOP's and HACCP

Beginning on the effective date of this final rule, establishments will no longer be required to submit drawings and specifications of facilities to FSIS for approval before beginning inspected activities or before remodeling facilities. They will no longer be required to use only FSIS-approved utensils and models of equipment.

Establishment operators must be aware of two things, however. First, in carrying out sanitation SOP's required by the Pathogen Reduction/HACCP regulations, if corrective action is necessary to maintain or restore sanitary conditions, an establishment may have to repair or replace facilities or equipment. FSIS inspectors will be verifying the establishment's operation of its sanitation SOP's. If, during verification activities, inspectors find that the SOP's are not being effectively implemented, they will have the full range of compliance measures available, including the rejection of equipment and areas of the establishment. It will be the responsibility of the establishment to take action with respect to any equipment or facilities that may be causing a sanitary hazard.

Second, in conducting the hazard analyses required to develop its HACCP plan, an establishment must determine all factors that may contribute to the emergence of hazards and the measures necessary to prevent or minimize those hazards. This means that the establishment's facilities and equipment must be designed to permit the process governed by the HACCP plan to be carried out. The facilities and equipment must be capable of meeting the applicable processing requirements of a product, must be cleanable, and must not become a source of hazards to the product. For example, facilities and equipment should be maintained so that product is not exposed to physical hazards such as paint chips, rust particles, or loose machine parts.

Establishments will be responsible for consulting with equipment manufacturers as necessary to complete their hazard analyses and identify appropriate critical control points (CCP's) while developing their HACCP plans. Establishments will be expected to take appropriate corrective actions whenever they find deviations from process critical limits while operating their HACCP systems. The actions necessary to correct a problem may, at times, require maintenance, repair, or replacement of equipment or facilities.

FSIS personnel will verify that establishments are effectively operating their HACCP systems. If FSIS finds a pattern of recurring hazards to product caused by facilities and equipment, the Agency has, and will exercise where appropriate, the authority to take action on product, equipment, or facilities. In those situations where FSIS finds a pattern of recurring hazards to product, it will be indicated that the HACCP plan is inadequate and the plan may have to be redesigned and revalidated.

Improving the establishment's facilities and equipment could well be among the steps necessary to redesign and revalidate the HACCP plan.

FSIS findings will not be directed primarily at the acceptability of facilities and equipment *per se*, but at the functioning of the HACCP plan in operation. In other words, if hazards to product are not being prevented or critical control points are failing, the failure may be the result of inadequate facilities or equipment and the establishment will be required to correct the problem.

Equipment and Utensils

FSIS will no longer evaluate equipment or utensils for acceptance. As mentioned earlier in this document, the final edition of MPI-2, *Accepted Meat and Poultry Equipment*, is being

published for reference purposes. Adequate sanitary design of equipment will be ensured through establishment implementation of SSOP's and HACCP plans.

Equipment and utensils must continue to meet the general standard that they are of a material and construction that will facilitate thorough cleaning and cleanliness in preparing edible product and must not interfere with or impede inspection procedures. (9 CFR 308.5(a), 308.15, 381.53(a)(1).) FSIS has authority to prevent the use of equipment or facilities that pose a threat to public health or interfere with inspection. FSIS must be notified in advance of any changes to facilities or equipment that may interfere with or force changes to FSIS's inspection operations.

PQC Programs

With respect to PQC programs, under this final rule inspectors will verify that establishments have written PQC programs on file, with data and information available to the inspectors, and that the process limits prescribed by the programs are being met. The establishments will be responsible for developing PQC programs that meet the regulatory requirements but there is no requirement for the programs to be approved in advance of their use. The establishments may seek advice from the Agency concerning requirements for such programs. As mentioned previously, draft guidance material on PQC programs is provided in Appendix B to this document.

Disposition of FSIS Files on Establishment Facilities

In concluding its prior approval activity for establishment drawings and specifications, FSIS will archive or otherwise dispose of the files of its facilities review staff. Establishment drawings and specifications and files, many of which contain proprietary information, will be destroyed with appropriate security under official supervision.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 12866 and Effect on Small Entities

FSIS is eliminating prior approval requirements for establishment drawings and specifications, equipment, and certain partial quality control programs. Concurrently with this final rule, FSIS is restructuring inspection activities to focus more attention on the ability of establishments to maintain a sanitary environment. These actions, in addition to implementation of the sanitation standard operating procedures required by the Pathogen Reduction/HACCP rule, will provide the industry the flexibility for creating and maintaining a sanitary working environment without prescriptive command-and-control requirements.

Removing these requirements affects establishments subject to official inspection, firms producing and selling equipment currently subject to prior approval, firms providing expediting services to businesses seeking prior approval, and consumers. The final rule will reduce demands on FSIS resources which can be redirected to functions more critical to assuring food safety.

FSIS considered a number of alternatives, including that of making no rule changes, before adopting this final rule. The Agency rejected the alternative of no rule changes because not changing the regulations would leave in place a prescriptive regulatory regime for equipment, facilities, and processes that conflicts in a material way with the objectives of the Pathogen Reduction/HACCP final rule. Under HACCP, establishments will assume responsibility for sanitation and for building science-based, preventive process controls into the food production system to reduce or eliminate food safety hazards. This will include taking responsibility for ensuring that facilities, equipment, and processes conform with sound sanitation principles and food safety performance standards. The existing requirements can also impede the ability of establishment management to implement, on a timely basis, better and more innovative food safety strategies.

Alternatives to facilities and equipment prior approvals that FSIS considered included development by FSIS of detailed standards to be published in booklets with periodic updates, recognizing industry organizations as prior approval authorities, and establishing general performance standards similar to FDA-recognized good manufacturing practices. Another alternative which would have provided prior approval

services on a voluntary, user-fee basis, was also considered.

FSIS rejected the alternative of publishing booklets containing detailed facility and equipment standards because, although establishments would assume responsibility for determining whether their facilities and equipment comply with the standards, establishments would remain without flexibility to implement innovative technologies that appear to depart from the written standards. It is also likely that, under this alternative, the Agency would continue to exercise discretionary prior approval authority over the introduction of new food safety technologies. Moreover, the Agency's inspection of facilities and equipment for compliance with the published standards would divert resources needed to verify SSOP's and HACCP systems. As mentioned above, however, FSIS is publishing draft guidance material on facilities and equipment as Appendix A of this document.

FSIS also rejected the alternative of officially recognizing industry organizations as prior-approval authorities for facilities and equipment. As mentioned earlier in this document, although such services may be beneficial to some establishments, many will not need and some will be unable to use such services. Thus, FSIS does not intend to provide official accreditation or certification of such services. The Agency's verification of SSOP and HACCP systems is intended to be its primary means for determining the adequacy of establishment food safety protective measures, including those measures that depend on well designed and maintained facilities and equipment.

FSIS also rejected the alternative of continuing its prior approval of facilities and equipment on a user-fee basis. This alternative had essentially the same drawbacks as the alternative of no rule changes. It would not have appropriately separated the roles of the establishment and the Agency. It would have perpetuated adherence to prescriptive design standards rather than setting food-safety performance standards for establishments to achieve. Finally, this alternative would have continued to pose the same regulatory obstacles to innovation as the current system.

FSIS chose the option of eliminating prior approval requirements for facilities and equipment, while maintaining the general food safety standards in the existing regulations. This action will remove regulatory obstacles to innovation and command-and-control requirements inconsistent

with the objectives of the Pathogen Reduction/HACCP final rule and the Agency's food safety regulatory strategy and will yield immediate and near-term benefits. As stated in its December 29, 1995, advance notice of proposed rulemaking, the Agency is considering replacement of more of its detailed regulatory requirements with performance standards. Such changes will be addressed in future documents.

The alternatives to PQC prior approvals were market sampling of finished products, mandating additional in-plant controls, sampling finished products for chemical analysis, and general requirements and standards for PQC programs.

FSIS regards market sampling as a potentially useful tool for enforcing the statutes prohibiting commerce in adulterated and misbranded meat and poultry products and for checking the effectiveness of establishment process controls. Sampling and testing products in the marketplace can also help in addressing food safety hazards arising in post-processing distribution of meat and poultry products. However, the Agency did not see a need for specific regulatory requirements concerning such sampling.

The alternative of mandating additional in-plant controls in lieu of PQC prior approvals would result in prescriptive, command-and-control requirements and restrict the scope for establishment food safety innovations, thereby defeating the purpose of this rulemaking.

In-plant sampling of finished products for chemical analysis also is a potential tool that FSIS has used to verify the effectiveness of in-plant controls. The Agency saw no need, however, for a specific regulatory mandate to conduct such sampling and analysis.

FSIS chose the option of providing general requirements for PQC programs that establishments would have to meet. This option seemed to provide establishments with the most flexibility in implementing PQC programs and a standard applicable to a range of processes.

Benefits of the Rule

Approximately 6,200 federally inspected meat and poultry establishments will no longer be required to submit blueprints, drawings, and specifications to FSIS for prior review and approval. FSIS reviewed an estimated 2,100 to 2,900 submissions in FY 1994. The range of the estimate is attributable to the fact that an indeterminate number of blueprints were returned to establishments and resubmitted to the Agency, some several

times, before being accepted. The cost of receiving FSIS approval for drawings and specifications and changes they represent includes the administrative, mailing, and labor costs associated with preparing the required Agency forms. The labor cost is estimated at 30 minutes for each submission. Assuming an hourly wage or per-hour salary of \$20-\$25 for each person submitting blueprints and specifications and the FSIS form, the annual cost to the industry for making these submissions is in the range of \$21,000 to \$40,000. This figure is an estimate of the savings accruing to industry by removing the requirement for prior approval.

As many as 1,500 establishments per year submit for approval PQC programs or amendments to PQC programs. FSIS receives a total of 1,900 submissions each year. A typical PQC program, prepared according to FSIS guidelines, can be written up in about 4 hours by an individual earning \$20 to \$25 per hour. Removing the requirement for prior approval of PQC plans is estimated to save the industry \$150,000 to \$190,000 per year.

FSIS receives approximately 2,500 submissions for approval of equipment each year. The cost of these applications generally falls on equipment manufacturers rather than the meat and poultry firms subject to inspection, although a few meat and poultry establishments make some of their own equipment or equipment modifications. FSIS estimates that the costs to manufacturers of applying for equipment approval are comparable to the costs to establishments of submitting blueprint and establishment specification approvals. Based on 30 minutes per submission, a labor cost of \$20-\$25 per hour, and 2,500 submissions annually, the annual cost savings from removing the prior approval requirement for equipment will be in the range of \$25,000 to \$32,500. In addition, approximately 650 applications for approval are contingent on in-plant trials, which involve some added costs to manufacturers and meat and poultry establishments. The Agency has no estimate of these costs to include in this analysis.

The elimination of blueprint prior approvals will remove a source of income for approximately 20 small firms, known as "expeditors," that represent official establishments for the purpose of labeling and blueprint approval. On the basis of information submitted during the comment period, the Agency understands that approximately 35 percent (or about 735 to 1,015) of the annual blueprint submissions to the Agency are made

using expeditors. The estimated annual total value of blueprint expediting is about \$300,000 to \$400,000 for the companies involved. Since the income lost to the expeditors will be transferred to meat and poultry firms, it is not a cost of the final rule.

The benefits directly resulting from the elimination of prior approval requirements in accordance with this rulemaking are indicated in Table 1. There also will be additional, unquantifiable benefits resulting from fewer demands on establishment management, greater incentives to adopt innovative practices, and the enhanced ability to make changes quickly, which the prior approval system and its inherent delays inhibit. Also, the delays inherent in the prior approval process, which can be translated into lost production time, will be eliminated.

Moreover, it is unlikely that any inspection finding of adulterated product or insanitary conditions under the amended regulations will result in increased costs to the industry for rebuilding or remodeling facilities. Establishments planning substantial investments in new construction typically consult with local authorities and experts with up-to-date knowledge of food establishment construction before beginning major projects.

In addition to the benefits to firms from eliminating these prior approval requirements, FSIS expects to benefit by reallocating about \$2.3 million to high priority food safety needs. Currently, the Agency allocates about 15 staff-years (\$750,000) to reviews of equipment, 20 staff-years (about \$1 million) to reviews of drawings and specifications, and 11

staff-years (\$550,000) to review and approval of PQC programs. The true social benefits to be expected are the improvements in food safety that will flow from reallocating these resources to more important food safety-related tasks.

Costs of the Rule

As is currently the practice, establishments will continue to be required to take corrective action or cease operations if any product has been adulterated or prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health, because of deficient facilities and equipment. A finding of product adulteration or insanitary conditions will entail corrective action which, in some cases, may involve reconstruction, remodeling, or redesign of facilities and equipment. However, it is unlikely that this rule will increase the level of inspection findings that result in such reconstruction, remodeling, or redesign primarily because, as mentioned, most establishments consult with knowledgeable authorities before major construction or installations. Also, proper operation of sanitation SOP's and HACCP systems will reduce the occurrence of adverse inspection findings.

Under existing regulatory requirements, facility and equipment plans submitted to FSIS for prior approval were rejected due either to errors in paperwork or to deviation from specific design criteria developed by FSIS. Under the final rule, establishments will be permitted to

initiate and complete construction or introduce new equipment without submitting any paperwork to FSIS. In addition, FSIS will eliminate design-related criteria currently utilized to evaluate the acceptability of facilities and equipment. Establishments will not have to incur costs for reconstruction, remodeling, and redesign because the facility or piece of equipment does not match a specified design criterion, blueprint, or equipment specification.

In the absence of prior approval, FSIS will focus inspection on whether establishments are maintaining a sanitary environment. Under this final rule and the Pathogen Reduction/HACCP regulations, establishments will assume greater control over their production practices to ensure that a sanitary environment is maintained. Currently, many establishments utilize the services of architects, engineers, and other experts to design facilities and equipment for use in meat and poultry establishments. Under the regulations requiring prior approval, these experts ensured, among other things, that FSIS design specifications were met. Without prior approval, establishments may require these experts to provide more information on the procedures necessary for maintaining facilities and equipment in a sanitary condition, which could increase the costs for these services. However, this is consistent with the need for the industry to assume greater responsibility for its operations. Any cost increases for these services will be commensurate with the transfer of responsibility from FSIS to the industry, and will not be a social cost attributable to the rule.

TABLE 1.—BENEFITS TO FIRMS FROM ELIMINATING PRIOR APPROVAL REQUIREMENTS

Action	Firms with more than 500 employees	Firms with fewer than 500 employees	All firms	Information collection burden reduction—all firms (in hours)
Remove blueprint and specification approval	\$1,260–2,400	\$19,740–37,600	\$21,000–40,000	701
Remove equipment approval	2,500–3,250	22,500–29,250	25,000–32,500	2,990
Remove PQC approval	9,000–11,400	141,000–178,600	150,000–190,000	540
Total	12,760–17,050	183,240–245,450	196,000–262,500	4,321

Regulatory Flexibility Assessment

The Administrator has determined that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–12), this final rule will not have a significant economic impact on a substantial number of small entities. The entities affected by this final rule are inspected meat and poultry establishments, equipment suppliers, and companies representing official establishments to

the Agency for the purpose of obtaining blueprint approvals. Most of these are small entities.

The final rule is expected to have a beneficial effect on small and large entities, on both those regulated under the FMIA and PPIA and some that are not regulated under the inspection laws but which are affected by the Agency's review of their products, e.g., suppliers

of equipment used in inspected meat and poultry establishments.

There are about 5,800 federally inspected small establishments. In this analysis, FSIS is using the Small Business Administration (SBA) business size standards (13 CFR 121.201) that apply to meat packing establishments, establishments that produce sausages and other prepared meats, and poultry slaughtering and processing

establishments. A small establishment in any of these categories is considered to be one with 500 or fewer employees. Under current regulations, all establishments are required, as a condition of receiving inspection, to submit blueprints, drawings, and specifications of new or remodeled facilities to FSIS for review and approval. Under this final rule, establishments will continue to incur the cost of preparing blueprints and specifications for construction and major installations. However, they will no longer bear the cost of submitting these drawings and specifications to the Agency for review because the requirement to do so is being eliminated.

The savings to be obtained by eliminating FSIS approval for drawings and specifications and the changes they represent includes the administrative and mailing costs and the time (resources) required to fill out the required Agency form ("Submission and Approval of Plans and Specifications," FSIS-5200-S), which is estimated at 30 minutes each submission. As mentioned above, the annual savings to the meat and poultry products industry from eliminating the requirement of making the submissions will be in the neighborhood of \$21,000-40,000. FSIS does not consider this savings to be significant. In addition to these direct savings, the largest potential savings to the industry from this final rule will be those savings associated with eliminating delays—of up to several weeks per submission—in obtaining approval. This estimated delay includes the time needed to resolve disagreements over plans and specifications, should such disagreements arise between the Agency and the establishment. This savings could be significant for some small entities, but there is no information to indicate that it will be significant for a substantial number of them.

The savings will not be significant for at least two reasons. First, establishments engaged in construction projects plan for the eventuality of an FSIS review, or at least are advised by knowledgeable food establishment architects and engineers to build FSIS review time into their project timelines. Costs are minimized because delays that do occur are anticipated. Second, under the current prior review and approval system, the Agency is able to exercise discretion expediting reviews of blueprints and facilities in specific cases to prevent economic hardship from occurring.

Eliminating the cost of blueprint prior approvals to small establishments

producing meat and poultry products will necessarily remove a source of income for about 20 small expediting firms that represent official establishments for the purpose of labeling and blueprint approvals. These expeditors are frequently able to shorten the time for these approvals and reduce the rejection rate on submissions because of their knowledge of Agency requirements and proximity to Agency offices. As mentioned above, the estimated annual total value of blueprint expediting is about \$300,000 to \$400,000 for the companies involved. This is a small part of the expeditors' total business, which is mainly that of expediting label approvals and consulting work. These firms may, however, experience an increased demand for their consulting services from inspected establishments who depended upon the Government's prior approval to assure they were in compliance with the regulations, who now need help from a third party to assure they are in compliance with the regulations. These 20 entities, in any event, do not constitute a substantial number of small entities.

The equipment acceptance procedure principally affects manufacturers or other vendors of equipment. The equipment manufacturers range in size from small to large concerns and, under the current regulations, depend on FSIS prior approval to be able to sell their products to inspected establishments. It is estimated that up to 90 percent of the equipment manufacturers and other applicants for FSIS equipment acceptance are small entities. According to the SBA small business size standards (13 CFR 121.201), a small food products machinery manufacturer is one that employs 500 or fewer people. A substantial number of these small entities, several hundred, will be affected by this rule. As shown in Table 1, equipment manufacturers and vendors that are classified as small entities will save in the aggregate between \$22,500 and \$29,250 from elimination of the cost of applying to FSIS for acceptance of equipment. As indicated previously, equipment manufacturers and vendors will save about \$10 to \$12.50 per year on each new equipment model or utensil from not applying to FSIS for acceptance. FSIS does not consider this effect of the rule to be significant, even if some firms have submitted several applications per year.

Also favorably affected by the approval process are inspected establishments that may want to install newly developed equipment or apply new technologies to improve their

operations. The savings from avoiding a delay before installation and operation of a newly developed piece of equipment, although it could be significant for a few entities, large or small, will not be significant for most establishments.

Finally, FSIS has determined that the elimination of prior approval of most PQC programs will not have a significant economic impact on a substantial number of small entities. Although prior approval will be eliminated, both large and small establishments subject to FSIS inspection will be permitted to continue to develop and implement PQC programs for their products and processes. Accordingly, the administrative delay for review that occurs under the present system will be eliminated.

It takes a minimum of 2 weeks for the Agency to review a typical PQC program, and as many as 1,500 establishments per year submit such programs or amendments to programs—a total of nearly 1,900 submissions per year—and about 90 percent of these establishments could be regarded as small entities. Therefore, roughly 1,100 establishments will avoid the costs associated with having to wait a minimum of 2 weeks for PQC approval, but it is not possible to identify what costs would be saved under these circumstances.

For these reasons, the Administrator has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The economic impact on such entities will, in most cases, involve the elimination of certain costs—some quantifiable, some not quantifiable—associated with doing business subject to Federal regulation, and hence will be beneficial to those entities. Though non-quantifiable, increasing the benefits that come from reducing an establishment's dependence on Government decisions is an important objective of the final rule.

Paperwork Requirements

FSIS has reviewed the paperwork and recordkeeping requirements in this final rule in accordance with the Paperwork Reduction Act. This final rule will substantially reduce "reporting" requirements for official establishments and other entities. FSIS estimates the total reduction in reporting to be 4,231 burden hours. The reductions will occur in the following information collection reports:

- ◆ 0583-0082, "Meat and Poultry Inspection; Application for Inspection, Sanitation, and Equipment Requirements and Exemptions":

Establishments subject to inspection will no longer have to submit blueprints and specifications along with Form FSIS-5200-5. The response time is estimated to be 30 minutes, and there are 701 total burden hours approved by the Office of Management and Budget (OMB) for this activity. Therefore, FSIS will request OMB to remove the 701 approved burden hours.

◆ 0583-0082, "Meat and Poultry Inspection; Application for Inspection, Sanitation, and Equipment Requirements and Exemptions": FSIS prior approval will no longer be required for the products of equipment companies that are used in official establishments. The response time is estimated to be 30 minutes for the prior approval of equipment. There are 2,990 total burden hours approved by OMB for this activity. Therefore, FSIS will request OMB to remove the 2,990 approved burden hours.

◆ 0583-0089, "Processing Procedures and Quality Control Systems": Establishments can continue to develop and implement PQC programs according to Agency guidelines. These establishments, with the exception of poultry irradiation facilities, are no longer required to submit a letter requesting approval of a proposed PQC program and a copy of the program to the Agency for approval prior to implementation. The response time is estimated to be 30 minutes for writing the request letter and sending the PQC program to FSIS. There are 600 total burden hours approved by OMB for this activity. In consideration of poultry irradiation facilities, 60 hours of burden will remain. FSIS does not foresee more than two irradiation facilities requesting FSIS approval of PQC programs. Therefore, FSIS will request OMB to remove 540 approved burden hours. The burden hours for PQC program development and reporting remain the same.

List of Subjects

9 CFR Part 304

Drawings, Information to be furnished, Grant or refusal of inspection, Meat inspection.

9 CFR Part 308

Meat inspection, Sanitation.

9 CFR Part 317

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 318

Meat inspection, Establishment-operated quality control.

9 CFR Part 319

Food grades and standards, food labeling

9 CFR Part 327

Imports, meat inspection

9 CFR Part 381

Poultry and poultry products

For the reasons set forth in the preamble, FSIS is amending 9 CFR Parts 304, 308, 317, 319, 327, and 381 of the Federal meat and poultry inspection regulations, as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

1. The authority citation for Part 304 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Section 304.2 is amended by revising the heading; removing paragraph (b); redesignating paragraphs (c) through (f) as paragraphs (b) through (e), respectively; and revising paragraph (a), to read as follows:

§ 304.2 Information to be furnished; grant or refusal of inspection.

(a) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

* * * * *

PART 308—SANITATION

3. The authority citation for part 308 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 308.2 [Removed and reserved]

4. Section 308.2 is removed and reserved.

5. Section 308.5 is amended by removing ", in the judgment of the Administrator," from the first and third sentences of paragraph (a); removing paragraphs (b) through (f); redesignating paragraph (g) as (b); and revising the section heading to read as follows:

§ 308.5 Equipment and utensils to be easily cleaned; those for inedible products to be so marked; PCB-containing equipment.

* * * * *

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

6. The authority citation for Part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 317.21 [Amended]

7. Paragraph (b) of § 317.21 is amended by removing the words "an FSIS approved" and adding, in their place, the word "a".

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

8. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

9. Section 318.4 is amended to read as follows:

a. Paragraph (d) is revised;
b. The words "or Partial Quality Control" are removed from the heading of paragraph (e);

c. Paragraph (e)(1) is amended by removing the words "or (d)" from the first sentence and both occurrences of the words "or partial quality control program" in the second sentence;

d. Paragraph (e)(2) is amended by removing the words "or program" from the first and second sentences;

e. Paragraph (e)(3) is amended by removing the words "or partial quality control program" from the first sentence;

f. The words "or Partial Quality Control" are removed from the heading of paragraph (g);

g. Paragraph (g)(1) is amended by removing the words "or a partial quality control program" and paragraph (g)(2) is amended by removing the words "or partial quality control program"; and
h. Paragraph (g)(3) is revised.

The amendments and revisions read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; establishment-operated quality control.

* * * * *

(d) Partial Quality Control Programs.

(1) Any owner or operator of an official establishment preparing meat food products who is required to have a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2)(i) This quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that

will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

(e) *Evaluation and Approval of Total Plant Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator, on the basis of an evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification.

* * * * *

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) * * *

(g) *Termination of Total Establishment Quality Control.*

(1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) * * *

(ii) * * *

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

* * * * *

10.–11. Section 318.7 is amended to read as follows:

a. Paragraphs (b)(3)(i) and (b)(3)(ii) of § 318.7 are revised; and

b. In the table in § 318.7(c)(4) under the Class of substance "Miscellaneous," the entry under the Substance "Ascorbic Acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate" is revised.

The revisions read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(b) * * *

(3) * * *

(i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the establishment has a partial quality control program as provided in § 318.4(d) that results in compliance with this provision, or

(ii) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in § 318.4(d) that results in compliance with this provision.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Product	Amount
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination under quality control.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

* * * * *

§ 318.19 [Amended]

12. Paragraph (e) of § 318.19 is amended in the first sentence by removing the words "total" and "partial quality control".

§ 318.308 [Amended]

13. Paragraph (b) of § 318.308 is amended by removing the words "an

approved" and "program" and paragraph (c) is amended by removing "and submitted to the Administrator for approval".

14. Paragraph (a) of § 318.309 is amended by removing the words "an approved" and "program" and paragraphs (b) and (c) of § 318.309 is amended by removing "and submitted to the Administrator for approval".

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

15. The authority citation for Part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

16. Section 319.5 is amended by revising the first two sentences of paragraph (e)(2) to read as follows:

§ 319.5 Mechanically Separated (Species).

* * * * *

(e) * * *

(2) A prerequisite for label approval for products consisting of or containing "Mechanically Separated (Species)" is that such "Mechanically Separated (Species)" shall have been produced by an establishment under an establishment quality control system.

* * * * *

§ 319.104 [Amended]

17. The last sentence in footnote 3 to the chart in § 319.104 is amended by removing the words "approved by the Administrator under § 318.4 of this subchapter."

§ 319.105 [Amended]

18. The last sentence in footnote 2 to the chart in § 319.105(a) is amended by removing the words "approved by the Administrator under § 318.4 of this subchapter."

PART 327—IMPORTED PRODUCTS

19. The authority citation for Part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

20. Paragraph (d) of § 327.6 is revised to read as follows:

§ 327.6 Products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

* * * * *

(d) Approval for Federal import inspection shall be in accordance with part 304 of this subchapter.

* * * * *

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

21. The authority citation for Part 331 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

22. Paragraph (a) of § 331.3 is revised to read as follows:

§ 331.3 States designated under paragraph 301(c) of the Act; application of regulations.

* * * * *

(a) Each establishment located in such a designated State, shall be granted inspection required under § 302.1(a)(2) of this subchapter only if it is found, upon a combined evaluation of its

premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

23. The authority citation for Part 381 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

24. Section 381.19 is revised to read as follows:

§ 381.19 Application for inspection; irradiation facilities.

All applicants for inspection whose operations include irradiation and other processing shall submit, to the Administrator, a proposed quality control system as provided in § 381.149 of this part.

25. Section 381.20 is revised as follows:

§ 381.20 Survey and grant of inspection.

(a) Before inspection is granted, FSIS shall survey the establishment to determine if the construction and facilities of the establishment are in accordance with the regulations. FSIS will grant inspection, subject to § 381.21, when these requirements are met.

(b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

26. Section 381.53 is amended by removing paragraphs (a)(2) through (a)(5) and paragraph (b); redesignating paragraphs (c) through (m) as paragraphs (b) through (l), respectively; and redesignating paragraph (a)(1) as paragraph (a) and revising it to read as follows:

§ 381.53 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling any edible poultry product or component ingredient shall comply with applicable provisions of paragraphs (b) through (l) of this section and otherwise shall be of such material and construction as will facilitate their thorough cleaning, ensure cleanliness in the preparation and handling of all edible poultry products, and avoid adulteration and misbranding of such products. In addition to these requirements, equipment and utensils shall not in any way interfere with or impede inspection procedures. Receptacles used for handling inedible

products shall be of such material and construction that their use will not result in adulteration of any edible product or in unsanitary conditions at the establishment, and they shall bear conspicuous and distinctive marking to identify them as only for such use and shall not be used for handling any edible poultry products.

* * * * *

§ 381.121d [Amended]

27. Paragraph (b) of § 381.121d is amended by removing the words "an FSIS approval" and adding, in their place, the word "a".

28. Section 381.145 is amended to read as follows:

a. Paragraph (d) of § 381.145 is revised;

b. The words "Programs or" are removed from the heading of paragraph (e);

c. Paragraph (e)(1) is amended by removing the words "or (d)" from the first sentence and both occurrences of "partial quality control program," from the second sentence;

d. Paragraph (e)(2) is amended by removing the words "or program" from the first and second sentences;

e. Paragraph (e)(3) is amended by removing "partial quality control program," from the first sentence;

f. The words "Programs or" are removed from the heading of paragraph (g);

g. Paragraph (g)(1) is amended by removing the words "or a partial quality control program";

h. Paragraph (g)(2) introductory text is amended by removing "partial quality control program," and paragraph (g)(2)(ii) is amended by removing the words "or program" from the first sentence; and

i. Paragraph (g)(3) is revised.

The amendments and revisions read as follows:

§ 381.145 Preparation of products to be officially supervised; responsibilities of official establishments; establishment operated quality control.

* * * * *

(d) *Partial Quality Control Programs.*

(1) Any owner or operator of an official establishment preparing poultry products who is required to have a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2)(i) This quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material

control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

(e) *Evaluation and Approval of Quality Control Systems.*

(1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator on the basis of an evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification.

* * * * *

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or quality control system for irradiation facilities to assure compliance with the requirements of the Act and regulations thereunder.

* * * * *

(f) * * *

(g) *Termination of Total Establishment Quality Control.*

(1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the

Administrator under the following conditions:

(i) * * *

(ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his designee.

* * * * *

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

* * * * *

29. Paragraph (a) of § 381.222 is revised to read as follows:

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

* * * * *

(a) Each establishment located in such a designated State, shall be granted inspection required under § 381.6(b) only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

§ 381.308 [Amended]

30. Paragraph (b) in section 381.308 is amended by removing "an approved" and "program" and paragraph (c) is amended by removing "and submitted to the Administrator for approval".

§ 381.309 [Amended]

31. Paragraph (a) of § 381.309 is amended by removing the words "an approved" and "program" and paragraphs (b) and (c) of § 381.309 is amended by removing "and submitted to the Administrator for approval".

Done, at Washington, DC, August 11, 1997.

Thomas J. Billy,
Administrator.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A—Guidance on Establishment Facilities and Equipment OVERVIEW

This Guidebook is intended for use by meat and poultry establishments in considering decisions about design and construction of their facilities, as well as the selection of equipment to be used in their operations. The material that forms the basis for this Guidebook is drawn principally from technical knowledge and experiences used by the Food

Safety and Inspection Service in making its prior approval decisions about the acceptability of facilities and equipment.

The Agency is no longer making these prior approval decisions for inspected establishments; however, the technical considerations on which those decisions were based may be of interest to establishments in the future. That is the material which is reflected in this Guidebook.

**Chapter 1
LOCATION**

Selecting the location for your establishment is an important factor in providing a sanitary environment for producing meat and poultry products. When selecting a location, you will need to consider the physical environment of the site, accessibility, separation of your premises from other businesses, common areas shared by you and other establishments, and whether or not you will conduct uninspected businesses such as retail stores or custom slaughter on or near your premises. This chapter provides guidelines you may wish to consider when the select a location for your establishment.

1. Site

The size of the site should allow for all buildings, parking lots, access roads, and future expansion. The site should be large enough to accommodate a potable water supply for your processing needs, and a sewage system that can efficiently handle liquid waste and process water created by your establishment. In addition, potential building locations should be evaluated for sanitation hazards. In determining that possibility, consider the following guidelines:

* To the extent possible, establishments should be located in areas free of industries that attract vermin such as sanitary landfills and junk yards.

* To the extent possible, establishments should be located in areas free of odors and airborne particulate matter that may be produced by neighboring industries or other outside sources, such as oil refineries, trash dumps, chemical plants, sewage disposal plants, dyeworks, and paper pulpmills.

* The prevailing winds are an important factor in site determination because substances emanating from more distant sources may be a problem if the winds carry them to the establishment site.

2. Separation of Official and Non-Official Establishments

Sometimes an establishment is located next to or in the same building as other businesses which are not under FSIS inspection. In those circumstances you should take great care to keep product from becoming contaminated from the operation of the adjoining business.

Chapter 2

LAYOUT

One of the most important decisions you make in building or modifying an establishment is how you plan the layout of your building, including the placement of rooms and equipment, product flow and people traffic patterns. Not only does a poorly designed establishment affect your productivity, but it may result in congested operations that can lead to unsanitary conditions. This chapter provides guidelines that you may wish to consider in planning any modifications to your existing establishment or in building a new one.

1. Flow of Operations

The direction in and means by which product moves or flows within a plant is an important but often neglected consideration that can have enormous influence on sanitation and the safety of finished products. From a product flow standpoint, all raw meat and poultry products ought to be considered as potentially microbiologically contaminated and handled accordingly. Product being processed should flow progressively from highest potential exposure to contamination to the least potential exposure to contamination, with intervening processes designed to remove or otherwise reduce the contaminants whenever possible. The flow of air and people should be just the opposite, moving from the cleanest areas progressively toward less clean areas.

When designing product flow, consider the following:

- * Moving product from raw to final cooked product areas to systematically reduce the risks of contamination along the way.
- * Locating trash dumpsters and receptacles so that they do not create a risk of product contamination.
- * Selecting rooms large enough to permit the installation of all necessary equipment with space for establishment operations and inspection.
- * Locating people passageways to provide maximum clearance to products, work areas, and production equipment.

- * Keeping truckways unobstructed.

2. People Traffic Flow

Inadequate control of the flow of people through product operational areas is one of the most serious risks for production contamination. People can act as carriers and bring from the outside contaminants such as dirt, debris, and vermin which are ideal vectors for microbiological growth and which can both directly and indirectly contaminate product. Ways in which you can reduce and control the flow of people include the following:

- * Establishment design should not require personnel not routinely assigned to specific work areas to be routed through those work areas. For example, personnel working in the live animal areas should not be required to travel through cooked product areas to use welfare rooms.
- * Welfare rooms, such as toilet rooms, dressing (locker) rooms, and cafeterias, should be designed to minimize contamination because of the traffic patterns of the people.

3. Separation of Raw and Ready-to-Eat Product

Cross contamination of ready-to-eat product by raw products may occur if the layout does not provide for separation of these products. To prevent cross contamination in the preparation of products, the following are guidelines for you to consider:

- * Exposed cooked product areas should be physically separated from other areas of the establishment. Non-pedestrian passage openings may be present for the transfer of product or supplies.
- * A ventilation system should be used to direct air flow away from exposed cooked product areas.
- * Environmental control equipment such as fans and evaporator condensation pans should not be located above the product.
- * Welfare rooms, dry storage, maintenance, box/carton make up, packaging, and palletizing areas should be separate, but adjacent to, the exposed cooked product rooms.
- * Cooked product should be covered in rigid containers to protect it from contamination while in storage.
- * Separate coolers and/or freezers should be available to use for exposed cooked product.
- * All cooking apparatuses for exposed products should have separate entry and exit portals.
- * No cooked product wash or reconditioning sinks should be used.

4. Perishable Product Rooms

Special care should be taken in perishable product rooms to inhibit growth of microorganisms in operations which could contaminate product. In addition, care should be taken to prevent contamination from other operations such as where raw ingredients are prepared. Non-meat or non-poultry ingredients should be prepared in a room or rooms separate from meat or poultry processing rooms. For example, preparation of raw vegetables for use in product should be performed in a room separate from meat or poultry processing rooms.

5. Edible and Inedible Products Rooms and Areas

Edible product can be easily contaminated by contact with inedible products, grease or sewage from inedible product areas. In order to prevent this contamination from occurring, consider the following in the placement of these rooms:

- * The flow of inedible and condemned product should be designed so that it does not come into contact with edible product.
- * An inedible products department should be separate and distinct from the areas used for edible products. Inedible product rooms, grease interceptors, and sewage treatment equipment must be located away from edible product rooms.
- * Hooded, closed chutes that lead directly from the slaughter room to the inedible handling room are designed to prevent objectionable odors from inedible and condemned products from entering edible products rooms.
- * If rendering facilities are not available at the establishment watertight storage facilities should be provided to hold these products before their removal to rendering plant. These storage facilities should be separate and apart from edible products rooms, and constructed to prevent unsanitary conditions including attraction or harborage for vermin.
- * Areas for inedible trucks should be paved and enclosed for ease of cleaning and to control odors and vermin.
- * Where necessary, the boiler room should be a separate room to prevent dirt and objectionable odors entering from it into rooms where meat products are processed or handled.

6. Byproducts for Use in Animal, Pet, or Fish Food

Establishments that process byproducts into animal, pet, or fish food should provide rooms for decharacterizing, chilling, packaging, or

otherwise preparing the byproducts. Consider the following guidelines when designing and constructing these rooms:

- * Byproducts to be used as animal, pet, or fish food should be stored separately to prevent cross contamination and commingling with edible products.

7. Coolers and Freezers

Coolers and freezers need to have enough space to refrigerate and store product. Product should be stored in a manner that will preclude conditions which may lead to contamination of product. The following guidelines will assist you in preventing conditions which could lead to contamination of your product:

- * Coolers and freezers, including doors, should be constructed of materials that can be readily and thoroughly cleaned, and durable, rigid, impervious to moisture, non-toxic, and non-corrosive. Freezer doors should be constructed and installed to prevent accumulation of frost.

- * Coolers and freezers should be equipped with floor racks, pallets or other means to ensure protection of product from contamination from the floor.

8. Dry Storage

Packaging materials and ingredients should be stored to preclude conditions which may lead to contamination of product. The following are guidelines which may assist you in the planning of your dry storage area:

- * Dry storage materials should be stored in a room dedicated to dry storage only.

- * The dry storage area should be constructed so that racks can be spaced away from the walls and passageways maintained between rows. This facilitates cleaning of the area. In addition, the construction should allow for all meat or poultry ingredients and/or packaging materials to be stored in closed containers on racks or pallets.

9. Incubation Room for Canned Products

A room or incubator for incubating samples of fully-processed canned meat or poultry must be provided in all establishments conducting regular canning operations. Consider the following guidelines when building this room:

- * An accurate time/temperature recorder must be provided. To prevent temperature variations, a means for air circulation should be provided.

- * Shelves should be provided to hold canned product. The shelves should be made of expanded metal or heavy gauge

wire mesh and be removable for cleaning.

- * The floor in the room should be pitched to a floor drain equipped with a removable screw-plug.

- * The door of the room should be equipped for sealing by the inspector, if necessary.

10. Vehicular Areas Outside the Building

Special care should be given in the design of vehicular areas outside your building, not only to provide room for trucks and other vehicles to operate without damaging your building, but to prevent unsanitary conditions which might contaminate product in your establishment. You should consider the following in designing your vehicular areas:

- * Areas outside the building where vehicles are loaded or unloaded should be paved with concrete or a similar hard surface. Hard surface areas allow these areas to be kept clean and eliminate the potential for water puddles or dust.

- * Areas outside the building where vehicles are loaded or unloaded should be drained. Drainage from the loading docks should be confined to the immediate area of the dock.

- * The vehicular areas should be large enough to accommodate the turning radius of the largest trucks or shipping vehicles used by the establishment.

- * The vehicular areas adjacent to the establishment should have hose connections for cleaning.

Chapter 3

WELFARE FACILITIES FOR ESTABLISHMENT EMPLOYEES

One source of potential contamination of product is cross contamination from employee welfare facilities. In designing and locating employee facilities, great care should be given to preventing overcrowding and congestion and to providing enough handwash sinks and toilets for your employees. This chapter provides additional guidelines that you may wish to consider in making any modifications to or building any welfare facilities for your employees.

1. Dressing (Locker) Rooms

Dressing rooms must be provided for employees. In addition to privacy considerations, these dressing rooms should be located where they will not be a potential source of cross contamination of product. Consider the following guidelines for these dressing rooms:

- * Dressing rooms should be separate from rooms or compartments where product is prepared, stored, or handled.

- * Dressing rooms should be separated from the toilet area.

- * Separate dressing rooms should be provided for each sex if both sexes are employed by the establishment.

- * Dressing rooms should have abundant, well-distributed light of good quality.

- * Separate dressing rooms for raw product and other product department employees will help prevent cross contamination of product.

- * Receptacles for soiled clothing should be provided adjacent to employees' dressing rooms.

2. Lockers

Lockers should be provided for employees clothing and personal items. To prevent insanitary conditions, consider the following guidelines when choosing the type of lockers and the arrangement and locations for them:

- * To prevent the potential for cross contamination, the location of lockers should be separate from rooms or compartments where product is prepared, stored, or handled.

- * Lockers should be large enough to store a change of clothing and other personal items.

- * For ease of cleaning, lockers should be constructed of materials that are rigid, durable, non-corrosive, easily cleaned and inspected, impervious to moisture, a light, solid color, with a smooth or easily cleaned texture, and have sloping tops.

- * Lockers should either be installed so that there is enough room under them that they can be easily cleaned and inspected, or they should be sealed to the floor.

3. Drinking Fountains

Sanitary drinking water fountains should be provided. Consider the following guidelines when installing drinking water fountains:

- * Drinking water fountains should be provided at convenient locations throughout the establishment to minimize the distance that employees need to travel to reach a fountain. This is especially important in preventing cross-contamination from employees working in raw or inedible areas and traveling to processing or ready-to-eat areas to use a fountain. Consider the following locations for placing drinking fountains:

- ** welfare areas including cafeterias, dressing (locker) rooms, and toilet rooms

- ** inspectors' offices

- ** edible product areas including kill floor, deboning, and cut-up areas

- ** inedible product areas

- ** immediately outside freezers and coolers

** storage areas

* Drinking water fountains should be connected to the potable water supply and either directly connected to the underfloor drainage system or should discharge through an air gap to a hub drain.

* Drinking water fountains should be other than hand operated, and if placed as part of handwash sink, should be located high enough to avoid splash from the sink.

4. Toilet Rooms

Toilet rooms can easily become a source of potential contamination of product. Care should be taken in the design of these rooms from their location in the establishment's layout to the number of toilets provided. Consider the following guidelines:

* Toilet rooms need to be separated from the rooms and compartments in which products are prepared, stored, or handled.

* Toilet rooms that open directly into rooms where meat products are exposed should have self-closing doors and should be ventilated to the outside of the building.

* Toilet rooms should be arranged so they are entered through an intervening dressing room or vestibule and not directly from a production or storage room.

5. Eating Rooms and Areas

To prevent employees from contaminating products or contaminating their food with microorganisms from the raw products or from their working environment consider the following:

* Separate eating rooms or areas should be provided for employees.

6. Handwash Sinks

One of the most important steps you can take to prevent cross contamination of product by your employees is to provide conveniently located handwash sinks. Handwash sinks are needed in toilet rooms, dressing (locker) rooms, and production rooms. Consider the following guidelines when making decisions as to where you need a handwash sink:

* Handwash sinks are needed near toilet rooms and dressing (locker) rooms. They should be other than hand operated. There should be hot and cold running water, soap, and towels. Single use towels should be used.

* Handwash sinks in welfare rooms and areas should have a combination mixing faucet delivering both hot and cold water with an high enough above the rim of the bowl to enable the washing of arms as well as hands.

7. Ventilation

In designing your welfare rooms, such as toilet and dressing rooms, care should be taken to make sure that they are ventilated to prevent odors from entering production areas. Consider the following guidelines:

* Welfare rooms that are not air conditioned should be mechanically ventilated through an exhaust fan taking air to the outside. Airflow from welfare rooms should be released outside the establishment.

* Toilet and dressing rooms that are located where no natural ventilation is available should be equipped with an exhaust fan (activated by a common switch with the lighting in the area) and a duct leading to the outside. Doors to dressing and toilet rooms ventilated in this manner should have a louvered section about 12 inches by 12 inches minimum in the lower panel to facilitate airflow.

8. Employees Working in Inedible Product Areas

Association of employees working in inedible product areas with other employees through common welfare rooms increases the risk of cross-contamination of product. To minimize this risk to product, consider the following guidelines:

* Separate welfare rooms for employees working in areas such as hide cellars, condemned or inedible product rooms, or live animal holding areas, from welfare rooms of other employees working with raw or heat processed, exposed, edible product.

Chapter 4

CONSTRUCTION

A frequently overlooked area of construction design is the selection of appropriate construction materials for the establishment. This chapter provides guidelines for construction and the selection of construction materials that you may wish to consider when making modifications to your current establishment or building a new one.

1. Building Construction Materials for Rooms (Finished Surfaces)

Production and storage areas need to be constructed with materials that are readily and thoroughly cleaned. Product in production and storage areas is at risk for contamination from indirect contact with materials used for construction of the building. In order to be readily and thoroughly cleaned, building construction materials in production and storage areas must be:

- * Rigid and durable.
- * Non-toxic and non-corrosive.

- * Impervious to moisture.
- * A light, solid color such as white.
- * Smooth or textured with an easily cleaned, open pattern, for example, a pattern where the veins and depressed areas are continuous or have an outlet and are not enclosed.

In addition, consider the following guidelines for selecting construction materials:

* In non-production and non-storage areas, building construction materials should be easy to clean thoroughly.

* Special consideration should be given before using wood as a construction material.

** Wood is absorbent and can absorb not only water but other substances including chemicals that create a risk for contamination of meat or poultry products.

** Wood is easily damaged and may create wood particles (splinters) that contaminate meat or poultry products.

** If wood is used as a construction material in exposed product areas of the official establishment, it is recommended that the wood be milled smooth and completely sealed with a coating to prevent the wood from adulterating meat or poultry product. The coating should be able to be readily and thoroughly cleaned durable, rigid, impervious to moisture, non-toxic, and non-corrosive.

** The use of hot linseed oil to treat or coat wood in exposed product areas is not recommended because it promotes the growth of molds and fungi.

2. Floors

In addition to any obvious debris on a floor, product can become contaminated by the flooring or microorganisms living in debris in tiny crevices in the floor. In order to avoid these sources of contamination, consider the following guidelines when selecting and installing flooring in your establishment:

* Floors in areas where product is handled or stored should be constructed of durable, easily cleanable materials, and be impervious to moisture. Commonly used materials are concrete, quarry tile, brick, and synthetic material.

* Floors should be installed and maintained to reduce the likelihood of cracks, depressions, or other low areas that would accumulate moisture.

* Floors where operations are conducted should have a slip-resistant surface. Good results are obtained by using brick or concrete floors with abrasive particles embedded in the surface. Concrete floors should have a rough finish.

* Floors should be sloped to avoid puddles or depressions within the slope where water will stand.

3. *Coving/Curbs*

Coving is used at the wall-floor juncture, column (post)—floor juncture, and equipment support-floor juncture to provide a smooth transition for ease of cleaning and inspection. Consider the following guidelines when using coving or curbs:

* Coving in production and storage areas should include the following criteria:

** All seams should be tight-fitting and sealed to eliminate all cracks and crevices which may shelter insects, vermin, and microorganisms.

** The coving should eliminate any sharp angles that allow the accumulation of materials.

* Curbs should be provided to protect walls and wall finishes. Curbs should be high enough to protect the walls from pallets, trucks, or containers used in the establishment. Coving should be provided at the base of the curb.

4. *Stairs*

In selecting stairs consider the following:

* Stairs should have solid treads and closed risers and should have side curbs of similar material.

5. *Catwalks and Access Platforms*

When installing catwalks and access platforms consider the following guidelines:

* Catwalks and access platforms in edible product handling departments should be constructed of materials that meet the same guidelines as flooring.

* Open grating should not be used for the flooring of catwalks and access platforms inside the establishment, particularly in production areas. Dirt and other debris from shoe soles can be scraped off by the grating and contaminate product, packaging material, and equipment.

* Catwalks and access platforms should not be installed over production lines and processing equipment.

6. *Interior Walls Including Posts and Partitions*

To prevent product from becoming contaminated by contact with interior walls, care needs to be taken in selection of materials for the finished surface of walls. Consider the following when selecting a finish:

* Interior walls, in areas where product is stored or handled, should be finished with materials that will make them susceptible to being readily and thoroughly cleaned and impervious to

moisture. Examples of such materials are glazed brick, glazed tile, smooth concrete, and fiberglass reinforced plastic (FRP).

* Walls should have a smooth texture, not one that is rough or uneven.

* Fasteners for wall covering material should be solid, smooth headed, and not have recesses which allows the collection of foreign material.

7. *Ceilings*

Ceilings, in areas where product is stored or handled, should be constructed to prevent the collection of dirt or dust that might sift through from the areas above or fall from overhead collecting surfaces onto equipment or exposed products. Therefore, it is recommended that ceilings and overhead structures be maintained free of sealing paint or plaster, dust, condensate, leaks, and other materials or defects. In addition, ceilings in areas where product is stored or handled should be constructed and finished with materials that can be thoroughly cleaned and are moisture resistant. Examples of such materials are smooth concrete and fiberglass reinforced plastic.

8. *Windows and Skylights*

Windows (and skylights) can be a potential source of contamination of product by dirt, water, debris, or broken glass. Consider the following when selecting and installing windows:

* All outside windows, except for those in receiving and feed rooms, should have protection to exclude insects, birds, and other vermin.

* Window ledges should be sloped about 45 degrees to prevent the accumulation of dirt, water, or debris.

* To avoid damage to window glass from impact of hand trucks and similar equipment, the sills should be at least 3 feet above the floor.

* Windows that are installed in walls in exposed product rooms should have panes of acrylic or polycarbonate plastic or other shatter-proof material.

9. *Doorways and Doors (General)*

Doors are barriers that allow the movement of product and people, but also present a barrier to contamination such as dirt, insects, and other vermin as well as the microbiological hazards that they carry. The door type, construction material, and room in which the door is located are all important considerations when doors are installed in the establishment. Doors are important in maintaining sanitary conditions especially in production and storage areas. In production and storage consider the following guidelines for doors:

The most effective doors have the following characteristics:

* They are impervious to moisture.

* They are tight fitting to minimize air exchange and to prevent the entry of insects and vermin into the establishments.

* They are self-closing and used throughout the establishment, especially in areas where toilet rooms open directly into rooms where meat and poultry are exposed, to prevent contamination of products with odors and their associated contaminants.

* They are high and wide enough to allow the movement of exposed product through the doorways without it coming into contact with the door or jamb.

* They are rigid and durable, and the junctions at jambs, walls, and floors are sealed to eliminate all cracks and crevices for debris, insects, and dirt to collect.

* Doors that open directly to the outside of the building from production rooms should have an intervening closed space, such as a vestibule or enclosed lock, to prevent the direct access of contaminants and microbial organisms to areas inside the establishment.

10. *Types of Doors*

In selecting a type of door for your establishment you need to consider the location of the door and whether or not product will be traveling through it. The following guidelines for different types of doors may be useful to you when selecting a door:

* The horizontal double-swinging, impact door is a bi-parting, inflexible panel door with plastic windows (vision panels) that swings only in the horizontal plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up, vertical sliding or horizontal sliding door.

** Because this door must be manually opened, the door can be damaged creating sanitation and maintenance problems.

* The horizontal sliding door (manual and automatic) is a single or bi-parting, inflexible door that moves only in the horizontal plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or vertical sliding door.

** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.

* The vertical sliding door (manual or automatic) is a single, inflexible panel door that moves only in the

vertical plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or horizontal sliding door.

** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.

* The overhead garage-type door (manual or automatic) is a hinged, multi-paneled door that moves from the vertical to the horizontal plane. If you select this door, consider the following:

** This door may be an excellent choice for sheds or buildings used to store equipment, such as a lawn mower, that is used for the outside maintenance of the establishment's property.

** It is recommended that these types of doors not be used in exposed product areas or areas subject to wet clean-up because these doors have spaces between the panels that allow the collection of product, such as meat and fat, as well as contaminants.

* The roll-up door (manual or automatic) is a single flexible panel door that moves only in the vertical plane and when open, coils tightly onto a drum assembly. If you select this door, consider the following:

** This door can be an excellent alternative especially where space for opening a door is limited.

** Several additional features should be installed on this type of door to make it an effective barrier against contamination.

* The air curtain or air door is a door that uses a layer of air generated by mechanical fans to separate two rooms or areas. If you select this door, consider the following:

** This door needs to be carefully selected, installed, and maintained to be effective.

** If an air imbalance (pressure imbalance) develops at the door opening, the separation effect may be diminished or eliminated. Air imbalance can occur from air flow changes from any other openings in the rooms especially other doors.

** The movement of the air can stir up contaminants, such as dirt and dust, if the area around the door is not kept clean.

Chapter 5

LIGHTING, VENTILATION, REFRIGERATION, AND EQUIPMENT

Controlling the manufacturing environment is important in maintaining a sanitary environment in meat and poultry operations. This chapter provides guidelines concerning lighting, ventilation, refrigeration, and

equipment for meat and poultry establishments that you should consider in building or modifying an establishment.

1. Lighting

Well-distributed, good-quality artificial lighting is needed at all places where natural light is unavailable or insufficient. Lighting is critical to maintaining a sanitary environment for slaughter and processing operations. Without adequate lighting, insanitary conditions are often difficult to see and correct. When selecting and installing lighting systems, consider the following requirements:

* Light fixtures in rooms where exposed meat or poultry is handled should ensure maximum safety, to preclude contamination of products with broken glass and prevent the collection of dirt, product, and debris on lamp surfaces, including fixture surfaces not easily cleaned or inspected.

* Lighting must be intense enough to allow both the establishment and inspection personnel to see insanitary conditions and product contamination. The intensity of lighting is measured in foot candles. The following charts provide recommendations for minimum foot candles for artificial lighting:

TABLE 1.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN MEAT ESTABLISHMENTS

Area	30 ft. candles	50 ft. candles
General lighting (in areas where animals are killed, eviscerated, and products are processed or packaged)	X	
Offal cooler	X	
Carcass coolers	X	
Freezers	X	
Dry storage	X	
Ante-mortem inspection	X	
Suspect pen inspection area		X
Inspection stations		X
Establishment quality control inspection areas		X
Reconditioning and reinspection areas		X
All other areas	X	

TABLE 2.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN POULTRY ESTABLISHMENTS

Area	30 ft. candles	50 ft. candles	200 ft. candles
Ante-mortem inspection	X		

TABLE 2.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN POULTRY ESTABLISHMENTS—Continued

Area	30 ft. candles	50 ft. candles	200 ft. candles
Inspection station (traditional)		X	
Inspection station (NELS/SIS/NTI)			X
Pre and post chill inspection areas			X
Reconditioning and reinspection areas			X
Establishment quality control inspection areas			X
All other areas	X		

2. Ventilation

There should be enough ventilation for all areas of the establishment including workrooms, processing, packaging, and welfare rooms to ensure sanitary conditions. A good ventilation system is important to the production of wholesome meat and poultry products. Without controlling the quality of the air coming into the establishment, products may become contaminated with dust, insects, odors, or condensation. When designing your ventilation systems, you should consider the following guidelines:

* The ventilation system should be designed so that turbulence is avoided. The longer the distance the air has to flow, the greater the resistance the air encounters not only from static air, but from solid objects such as walls, equipment, people, and product.

* The ventilation system should be designed with the size of the establishment in mind. The larger the facility, the greater the volume of air that must be moved.

* The ventilation system should be designed to compensate for changes in outside temperature and humidity that cause condensation problems within the establishment.

* Screens and filters should be used where needed to screen out dust, odors, and insects brought in from the outside to prevent product contamination.

* Mechanical ventilation should be used to bring in fresh air to areas where natural ventilation is inadequate.

* Ventilation should prevent vapor formation, such as steam or fog, that would affect sanitation or interfere with the inspector's ability to perform inspection.

* When exhaust fans are installed, provision should be made to provide enough outside make up air to prevent air from being drawn into and through docks, coolers, and production areas to the area served by the exhaust fan.

3. Equipment (General Design and Construction)

Equipment materials should comply with 21 CFR, Parts 170–190 of the Food and Drug Administration (FDA) regulations for direct food contact.

Equipment and utensils used for handling as preparing edible product or ingredient in any official establishment should be easily cleaned and not be a source of contamination. Consider the following guidelines when selecting equipment.

* All direct product contact surfaces should be smooth; maintained free of pits, cracks, crevices and scale; corrosion and abrasion resistant; non-absorbent; shatterproof; nontoxic; and not capable of migrating into food products.

* Equipment should not be painted on areas in or above the direct product contact area.

* Construction materials that are sources of contamination include cadmium, antimony or lead as plating or the plated base material, lead exceeding 5 percent in an alloy and enamelware and porcelain used for handling and processing product.

* Equipment should be designed and installed in such a way that foreign materials, such as lubricants, heat exchanger media, condensate, cleaning solutions, sanitizers and other nonfood materials, do not contaminate food products.

* Equipment is self-draining or designed to be evacuated of water.

* All product contact surfaces allow contact with cleaning solutions and rinse water.

* Clean-in-place (CIP) systems should have sanitation procedures that are as complete and effective as those for cleaning and sanitizing disassembled equipment. To remove all organic and inorganic residues, CIP systems should meet the following criteria:

** Cleaning and sanitizing solutions and rinse water should contact all interior surfaces of the system.

** The system should be self-draining, with no low or sagging areas.

** The pipe interiors should be highly polished (120–180 grit) stainless steel for easy inspection.

** Easily removable elbows with quick-disconnect mechanisms should be installed at each change of direction. Elbows should be short enough to

permit verification that the interior has been cleaned.

Chapter 6

WATER SUPPLY

The water supply should be ample, clean, and potable with adequate pressure and facilities for its distribution in the establishment and its protection against contamination and pollution.

1. Potable Water

An adequate supply of fresh clean water is of primary importance in plant operations. The first requirement is that the water supply to the plant be potable or safe for human consumption or food processing. The plant water supply must meet the potability standards in the National Primary Drinking Water Regulations issued by the Environmental Protection Agency (EPA).

2. Backflow

Public health officials have long been concerned about cross-connections that may permit backflow in potable water supply distribution systems. Cross-connections may appear in many forms and in unsuspected places. Reversal of pressure and flow in the water system may be unpredictable. Plumbing cross-connections between a potable and nonpotable water supply may constitute a serious public health hazard. There are numerous cases where cross-connections have been responsible for contamination of potable water and have resulted in the spread of disease. These concerns, as they relate to meat and poultry plants, deserve special attention. The problem is continual as potable water and piping systems are installed, repaired, replaced, or extended.

Two basic types of hazard may be created in piping systems: the solid pipe with valved connections and the submerged inlet. The solid pipe connection is often installed to supply an auxiliary piping system from the potable source. It is a direct connection of one pipe to another pipe or receptacle. Solid pipe connections may be made accidentally to waste disposal lines when it is incorrectly assumed that the flow will always be in one direction. An example would be connecting a line carrying used, nonpotable cooking water from a water jacket or condenser directly to a waste line without an air gap (see below). "Backflow" will occur with a submerged inlet if the pressure differential is reversed without an air gap. Submerged inlets are created when the outflow end of a potable water line is covered with water or other liquid.

The other liquid may not be potable. Submerged inlets could be created by a hose lying in a pool or puddle of water on the floor.

Once a cross-connection exists, any situation that causes a pressure differential with the potable line having the lower pressure can result in contamination of the entire water distribution system and potable water supply. This is called backflow and can be produced under a variety of circumstances as illustrated below:

* Backsiphonage is one form of backflow. It is caused by negative pressure in the delivery pipes of a potable water supply and results in fluid flow in the reverse direction. It may also be caused by atmospheric pressure exerted on a pollutant liquid source that forces the pollutant into a potable water supply system that is under vacuum. The action in this case is the common siphon phenomenon. The negative pressure differential that will begin the siphoning action is a potential occurrence in any supply line.

* Differential pressure backflow refers to a reversed flow because of backpressure other than siphonic action. Any interconnected fluid systems in which the pressure in one exceeds the pressure of the other may cause flow from one to the other because of the differential. This type of backflow is of concern in buildings where two or more piping systems are maintained. The potable water supply is usually under pressure from the city water main. Occasionally, a booster pump is used. The auxiliary system often is pressurized by a centrifugal pump, although backpressure may be caused by gas or steam pressure from a boiler. A reversal in differential pressure may occur when pressure in the potable system drops below that in the system to which the potable water is connected. The best method of preventing this type of backflow is the complete separation of the two systems and/or an air gap. Other safety methods involve the installation of mechanical backflow prevention devices. All methods require regular scheduled inspection and maintenance to ensure ongoing effectiveness of installed devices.

Some areas that you should consider providing some form of protection from backflow and back siphonage include the following:

* Water supply to pens for wash down or livestock watering.

* Water supply to compressor cooling systems, cooling towers, and boiler rooms.

* Water supply to cleanup systems, clean in place (CIP) systems, etc.

* Water supply to hose connections.

Various mechanical antibackflow devices are available to prevent backflow into a potable water supply system. Generally, the selection of the type and number of fail-safe devices should be based upon the degree of hazard from contamination. Additional considerations include piping size, location, and the need to test periodically the backflow devices to ensure proper operation.

There are six basic types of devices that can be used to correct cross-connections:

- * Air gap
- * Barometric loops
- * Vacuum breakers—both atmospheric and pressure type
- * Double check valves with intermediate atmosphere vent
- * Double check valve assemblies
- * Reduced pressure principal backflow preventers
- * Specific requirements concerning backflow can be found in local building and board of health codes.

Chapter 7

GENERAL PLUMBING FACILITIES

One of the most important factors to consider in the design and modification of establishments is the plumbing system. If the plumbing system is not properly installed, contamination of products can occur from flooding, back siphonage, stoppages and cross-connections with the potable water system. This chapter provides guidelines concerning the plumbing facilities, in meat and poultry establishments. For additional information on the design and modification of plumbing facilities, consult the National Plumbing Code.

1. Hose Connections and Hoses

There should be enough conveniently located hose connections with steam and water mixing valves or hot water connections provided throughout the establishment for cleaning purposes. Hose connections are important in promoting routine cleaning of the establishment. Consider the following guidelines when determining how many hose connections, location of hose connections, and storage of hoses:

- * The number of hose connections depends on the number of drains.
- * If a shut-off nozzle is provided on the hose after the hot and cold water mixing valve, the vacuum breaker at the hose connection to the mixing valve will not work. Vacuum breakers should be installed on the hot and cold water supplies prior to the mixing valve to prevent such problems.

* Hose connections should be provided with vacuum breakers to prevent back siphonage.

2. Establishment Drainage System

There need to be efficient drainage and plumbing systems for the prompt removal of liquid and suspended solid wastes from the processing environment. Consider the following guidelines when designing or modifying your drainage system:

- * All plumbing should be sized, installed and maintained in accordance with applicable state and local plumbing codes, ordinances, and regulations.
- * Drainage lines should be located so that if leakage occurs, it will not affect product or equipment.

3. Floor Drains

All parts of floors where operations are conducted should be well drained. There are two basic types of drains: point drains and trench drains. Point drains, the most commonly used drain in most areas, are located in strategic points in the room with the floor sloped toward the drain. The waste water flows over the surface of the floor until it reaches and is carried away by the drain. Trench drains involve a trough or trench that collects the waste from a larger area and directs the flow to a drain opening. The flooring is sloped toward the trench.

In a typical plant, one four-inch (10.16 cm) drainage inlet is provided for each 400 square feet (37.16 square meters) of floor space. A slope of about one-quarter inch per foot (2.08 cm per meter) to drainage inlets is generally adequate to ensure proper flow with no puddling. In dry production areas, where only a limited amount of water is discharged on to the floor, an adequate slope may be about one-eighth inch per foot (1.04 cm per meter). It is important that floors slope uniformly to drains with no low spots to collect liquid.

* The location of floor drains depends upon many factors such as the type of task conducted in the space, the geometric shape of the area drained, truck traffic patterns, and equipment locations.

* There are special drainage considerations in areas where there is a high volume of water usage. The water in trench drains should flow in the opposite direction of the product flow, for example, from the poultry evisceration to the picking areas.

* All parts of floors where wet operations or where floors are to be frequently hosed down should be pitched to floor or trench drains.

* Floor drains should not be located under equipment because it makes them inaccessible cleaning.

* Rooms without floor drains such as dry storage, large finished product coolers, and distribution warehouses may prefer to use mechanical cleaning machines instead of installing drains. Examples of such cleaning devices are floor scrubbers and dry/wet vacuum machines.

4. Trap Seals

Each floor drain should be equipped with a deep seal trap and vented properly to the outside. The purpose of such traps is to seal off the drainage system so that foul odors (sewer gases) cannot enter the plant. Effectiveness of the trap depends upon enough water remaining to constitute a seal. As water flows through the trap and down the drainpipe, suction is created that will pull the water out of the trap and break the seal unless the suction is broken by venting the drainpipe on the effluent side of the trap to the outside air. The seal can also be broken by evaporation of trapped water. This is not a problem in frequently used drains, but does occur where drains are seldom used.

5. Drainage Lines

All drainage lines must comply with local code requirements. They should be installed and maintained to be leakproof. To prevent drainage lines from becoming entrances into the plant for pests, including rats and mice, all lines must be equipped with effective rodent screens. Secure drain covers, in addition to keeping out pests, also serve to prevent blockage of the traps and drainage lines with product scraps or other material too large to flow freely.

6. Cleanouts

Cleanouts should be installed in the drainage system to prevent sewer blockages. Consider the following guidelines when installing cleanouts:

* Cleanouts should be located so they are readily accessible, and can be used without constituting a threat of contamination to edible products.

* To help avoid water puddling, cleanouts should be located on the "high lines" of floor slopes and away from traffic patterns.

Chapter 8

ESTABLISHMENT SEWAGE TREATMENT

The design and construction of sewage treatment facilities must comply with local code requirements. An improperly designed sewage system can contaminate the ground and water supply. This chapter provides

guidelines concerning sewage treatment at meat and poultry establishments that you may wish to consider in the installation of a sewage treatment facility.

1. Establishment Sewage Treatment

Sewage, one the most dangerous sources of human pathogens, should never be allowed to come into contact with products, equipment, utensils, or any food contact surfaces. When installing an establishment sewage treatment facility, consider the following guidelines:

- * The system should be large enough to handle the amount of sewage that the establishment produces and accommodate future increases.

- * If a private septic tank, pre-treatment, or treatment system is used, it should be designed and operated to prevent contamination of products.

- * The sewage facility should be located away from product operations and ingredient and packaging storage areas.

- * An area for cleaning solid waste containers with hot water, drains, and curbing should be located near any solid waste disposal facility.

2. Grease Catch Basins or Interceptors

Grease catch basins can be a source of contamination of products if not properly designed and located. Consider the following guidelines when constructing a grease catch basin:

- * Catch basins or interceptors for recovering grease should not be located in or near edible product departments or areas where edible products are shipped or received.

- * When a catch basin is located inside an establishment, it should be sealed with a gastite cover and located in a ventilated room.

- * Grease catch basins should be constructed so they can be completely emptied of their contents for cleaning.

- * The area surrounding an outside catch basin should be paved with impervious material, such as concrete, and drained.

Chapter 9

MEAT SLAUGHTER ESTABLISHMENTS

Although the flesh of healthy livestock is practically sterile, when the animal is killed many factors can contribute to contamination of the carcass including improperly designed and constructed slaughter facilities. This chapter provides guidelines for meat slaughter facilities to consider in building or modifying slaughter facilities.

Because different species of livestock need different slaughter facilities, this chapter is organized in the following way:

- * Sections 1 through 8 describe general guidelines for facilities that slaughter cattle, calves, sheep, goats, hogs, and equines.

- * Sections 9 through 37 describe additional guidelines for slaughter facilities as follows:

- * Sections 9 through 19 contain additional guidelines for cattle slaughter operations;

- * Section 20 contains additional guidelines for calf, sheep, and goat slaughter operations;

- * Sections 21 through 26 contain additional guidelines for hog slaughter operations; and

- * Section 27 contains additional guidelines for equine slaughter operations.

Note: The guidelines in this chapter are in addition to Chapters 1 through 8 which contain general guidelines which apply to all official meat and poultry establishments.

Meat Slaughter—General Facilities Guidelines

The following guidelines apply to all establishments that slaughter cattle, calves, sheep, goats, hogs and equines. If you are building or modifying an establishment that slaughters these species, consider these facilities guidelines to prevent contamination of carcasses during slaughter operations.

1. Livestock Pens

In addition to preventing contamination of the slaughter department and minimizing contaminates on the hides of the animals, proper design and construction of livestock pens prevent injury to the animals. Consider the following facilities guidelines when designing and constructing livestock pens:

- * Livestock pens should be located outside the slaughter department to prevent contamination of products from dust, odors, and other contaminates. If possible, the livestock pens should be separated from the department by full-height partitions of impervious material.

- * Livestock pens, driveways, and ramps should be free from sharp or protruding objects which could cause injury or pain to the animals.

- * Floors of the pens, ramps, unloading chutes, and runways should be constructed to provide good footing for livestock. Waffled floor surfaces and cleated ramps are effective construction designs.

- * Floors of the pens, ramps, unloading chutes, and runways should be sloped for drainage and cleaning.

- * Pen enclosures (except gateways) should be high and sturdy enough to prevent livestock from escaping.

- * Gates, fences, and chutes should have smooth surfaces that are easily cleaned.

- * Man gates or, if the walls are concrete, toe holds formed in the walls should be present to allow people to escape from pen enclosures in an emergency.

- * To help prevent livestock from slipping and falling on floors covered with excess water, thereby further contaminating their hides, water troughs should be provided with overflows located above or adjacent to pen floor drains.

- * Hose connections should be provided for cleanups.

- * Covered pens should be provided to protect crippled or downer animals from adverse climatic conditions. If held overnight, the pens should be large enough to allow the animals to lie down and have facilities for feed and water. Pens and driveways should be arranged so that sharp corners and direction reversals of driven animals are minimized.

- * A "U.S. suspect" or "U.S. condemned" pen should be available at all times and designed to allow for complete separation, including the drainage system, from other livestock.

2. Ante-mortem Inspection Areas

Ante-mortem inspection areas should be designed and constructed to facilitate inspection and to prevent animals from being injured. Consider the following guidelines in designing and constructing these areas:

- * To avoid delays in slaughter operations, pens for ante-mortem inspection should have the capacity for holding the maximum number of animals of the various species that will be slaughtered in a single day.

- * To facilitate the ante-mortem inspection of animals, a separate suspect pen with a squeeze chute should be provided, where the temperature of the animals may be taken.

- * At least 50 percent of the livestock pen, including the area where the suspect pen and squeeze chute are located, should be under a weather tight roof to provide an area for proper ante-mortem inspection in inclement weather.

- * Special consideration should be given to designing ante-mortem inspection facilities to allow for humane transporting of crippled or downer animals into the slaughtering department. Because crippled and downer animals have difficulty moving,

special doorways and hoists to transport them to the stunning area should be provided.

3. Slaughter Area

The slaughter area is one of the most difficult areas to keep sanitary because of the nature of slaughter operations. Consider the following guidelines in designing and constructing slaughter areas to minimize contamination of carcasses:

- * The slaughter area should be separated from the outside by a full-height partition or wall made of impervious material.
- * Any doors to the outside of the slaughter area should be self closing to minimize the risk of contamination, including contamination by vermin.
- * Slaughter areas should have floor space arranged to facilitate the sanitary conduct of operations and efficient inspection. For example, to prevent contamination of carcasses, truckways through which products are conveyed from the slaughter area to rooms such as the offal cooler, should be located so that the material is not trucked beneath rails from which dressed carcasses and products are suspended. For the same reason, personnel traffic should not move through lines of carcasses.

4. Stunning Areas Including Chutes and Alleys

Stunning areas, chutes and alleys, should be designed to prevent congestion, injury to animals, and minimize contamination of hides which can lead to contamination of the carcasses. Consider the following guidelines when designing these facilities:

- * All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be large enough for the species being slaughtered.
- * All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free from pain-producing restraining devices, sharp projections such as loose boards, exposed bolt ends, splintered or broken planking, protruding metal, and exposed wheels or gears.
- * All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free of unnecessary holes and openings where the animals' feet or legs may be injured.
- * Overhead gates should be covered at the bottom edge to prevent, injury to the animals.
- * Flooring should be constructed of roughened or cleated cement to reduce falls.

* Stunning areas should be provided for confining animals for stunning before bleeding.

* If ritualistic slaughter operations are conducted in the stunning area, shackles to confine the animals also should be provided.

* When captive bolt stunners are used, the stunning areas should be designed and constructed to limit the free movements of animals so that the operator can locate the stunning blow with a high degree of accuracy.

* When electrical stunning is used, the stunning area should be constructed so that any power activated gates will not cause injury to the animals.

5. Rail Arrangement and Truckways

To prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses. Consider the following guidelines when arranging rails in your establishment:

- * Consideration should be given to the type of rail and the rail speed when determining how rails are to be arranged.
- * Trim rails should be arranged so that carcasses pass the final carcass inspection position after the final trim.
- * To prevent the carcass from becoming contaminated by debris on the floor and from splashes during cleanups, the cooler rails should provide for clearance from the lowest part of the carcass to the highest point of the floor.
- * A room or area for washing gambrels, hooks, and trolleys should be provided. The room or area should have an exhaust fan in an outside wall to dispense steam.

6. Viscera Separation and Edible Byproducts Refrigeration

Because edible organs and parts (offal) are handled at temperatures conducive to bacterial growth, care must be taken in providing facilities for separation of viscera and for refrigeration of edible byproducts to prevent them from becoming contaminated. Consider the following guidelines for holding edible by products:

- * Facilities, such as viscera trucks or pans, should be provided for separating and handling viscera of the various species of animals to prevent commingling.
- * To prevent cross contamination, a separate cooler or a separately drained part of a carcass cooler should be provided for holding edible organs and parts (offal) under refrigeration.

* To convey the edible byproducts to a cooler, a truck with removable metal drip pans should be provided.

* To prevent cross contamination, establishment and inspection personnel from the slaughter department should be able to access the edible byproduct cooler without passing through a line of carcasses or through a congested carcass cooler.

7. Carcass Washing

Special facilities for washing inspected carcasses are needed to remove bone dust and other accidental contamination from the carcass. Consider the following guidelines when designing and constructing this area:

- * A separately drained area or an area that is sloped to a floor drain should be provided where inspected carcasses are washed.
- * If the carcasses are washed manually by establishment personnel, a platform should be provided to allow establishment personnel to be able to reach all parts of the carcass.

8. Retain Room/Compartment

* A retain room, cage, compartment, or receptacle may be required by inspection. Depending on the needs of inspection, consider the following guidelines for designing and constructing this room:

- * The retain room or compartment must be equipped for locking or sealing.
- * The room or compartment needs to be marked conspicuously "U.S. Retained."

* If the retain compartment is located in the cooler, the compartment should be separated from the remainder of the cooler to prevent cross-contamination of inspected and passed carcasses. The separation can be accomplished by creating a compartment constructed of partitions of corrosion resistant wire screen or flat expanded metal.

Cattle—Additional Facilities Guidelines

In addition to the guidelines (sections 1 through 8) for all establishments that slaughter livestock, the guidelines in the following sections 9 through 19 apply to establishments that slaughter cattle.

9. Cattle Dressing Layout

There are a number of different cattle dressing layouts that can be used in a cattle slaughtering operation. Depending on the number of animals slaughtered, rate of inspection, and number of inspectors, you should carefully consider your options for a layout for slaughter operations.

10. Rail Heights, Distances, and other Slaughter Area Dimensions

To assist you in planning the layout of your slaughter area, the following is a chart for recommended distances including rail heights, rail distances, and other cattle slaughter area dimensions:

TABLE 3.—GUIDELINES FOR DISTANCES IN CATTLE SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance	Horizontal distance
Bleeding rail (distance from rail to point of application of shackle to shackle foot—4 feet (1.2 m)).	16 feet (4.9 m)	
Dressing rails (trolley length—1 foot 3 inches (.4 m))	12 feet 3 inches (3.7 m)	
Beef cooler rails (trolley length—1 foot 3 inches (.4 m))	11 feet (3.4 m)	
Moving equipment—heights of conveyor rails, platforms, top of viscera inspection table.		
Dry landing area in front of stunning pen.		7 by 8 feet (2.1 by 2.5 m)
Curb of bleeding area to pitch plates (no header rails).		5 feet (1.5 m)
Between header rail and carcass washing rail, if parallel.		6 feet (1.8 m)
Between header or washing rails and wall of slaughtering room.		3 feet (.9 m)
Between center lines of dressing beds.		8 feet (2.5 m)
Between moving top table and dressing rail at inspector's platform.		5 feet 6 inches (1.7 m)
Area for sterilizing viscera inspection truck.		7 by 8 feet (2.1 by 2.5 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

11. Dry Landing Area

A dry landing area large enough to accommodate stunned animals removed from the stunning pen should be

provided adjacent to the stunning pen. Consider the following guidelines in designing and constructing this area:

- * The area should allow enough room for the livestock.
- * The dry landing area should be located and drained separately from the bleeding area.
- * The dry landing area should be enclosed by a fence high enough and sturdy enough to prevent escape of inadequately stunned animals.

12. Bleeding Area

To contain blood and prevent it from contaminating carcasses, a curbed bleeding area should be provided. Consider the following guidelines in designing and constructing this area:

- * The bleeding area should be located so that blood will not be splashed on stunned animals lying in the dry landing area or on carcasses being skinned on the cradle beds, if they are used.
- * The curb around the bleeding area should be located far enough from the dressing bed or cradle to allow room for the carcasses to be maneuvered into the bed or cradle.

13. Facilities for Head Removal

To avoid contamination of the carcasses from rumen contents, facilities for head removal need to be carefully designed:

- * Space should be provided for dehorning, flushing, washing, and inspecting heads; for storing heads on racks or trucks after removal from carcasses; and for head workup.
- * When a down hide puller is used, the head drop and head removal area should be curbed and drained.
- * A head wash cabinet should be provided.

14. Facilities for Hide Removal

To limit contamination by hides, a hide chute should be provided near the point where hides are removed from carcasses. Consider the following guidelines when designing and constructing these facilities:

- * The chute should have a hood of sturdy rust-resistant metal with a push-in door closely fitting a metal frame inclined so as to be self-closing. In order to evacuate airborne contaminants from hides such as scurf, dirt, spores, odors, and hairs, a vent pipe should extend from the hood vertically to a point above the roof.
- * Space needs to be provided between hide pulling and carcass evisceration to permit cervical inspection prior to viscera inspection.

15. Facilities for Feet and Udders

Because of the high risk of contamination of carcasses from feet and udders which have been removed from carcasses, special facilities, such as a chute or slide, should be used for transferring these parts to containers. Consider the following guidelines for these facilities:

- * A chute or slide should be used to avoid splashing of milk or other contaminants onto the carcasses, floor, equipment, and personnel.

16. Foot Platforms

Foot platforms installed for establishment employees performing various carcass dressing operations need to be carefully designed and installed to prevent contamination of carcasses. Consider the following guidelines:

- * If elevated foot platforms are used, they should be located so they do not touch skinned portions of the carcass.
- * If stationary platforms are used, they should be set far enough away from the dressing rail to prevent contact with the forelegs of cattle.
- * To provide space for operations and to prevent cross contamination by carcasses, push fingers or rail stops on powered conveyor or gravity flow rails should be spaced far enough apart to prevent contact between carcasses.

17. Viscera Trucks

In establishments with a limited rate of slaughter, viscera are usually placed in a specially designed handtruck for inspection. Consider the following guidelines for use of viscera trucks:

- * For ease of cleaning, viscera trucks should be constructed of stainless or galvanized steel.
- * Viscera trucks should have an inspection pan and a lower viscera compartment.
- * When viscera trucks are used, a separately drained area should be available for washing and sterilizing such equipment.

To prevent contamination of products, the washing facilities should be located at or near the point where condemned products are discharged from the trucks. When placed where splash might contaminate edible products, the truck washing area should have walls high enough to contain any splash.

18. Moving-Top Inspection Tables

In some establishments, viscera are placed on a moving-top table for inspection. These tables have special considerations as follows:

- * The table should be of a length that provides for evisceration, inspection, and viscera removal.

* A continuous cleaning and sanitizing system should be available for the table.

* To prevent contamination of products and the surrounding area, the viscera inspection table should have a drain under the table to prevent water from draining across the floor to other areas of the room.

* To prevent contamination of carcasses, the foot platform, handwash sinks, hand tool disinfection unit (sterilizer), boot washing cabinet, and boot storage locker should be located alongside the loading end of the table.

19. *USDA Post-mortem Inspection Station and Retain Rail*

Special facilities are needed for USDA post-mortem inspection for cattle.

Consider the following provisions that must be met when designing these stations:

* An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector.

* When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.

* A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.

* A handwash sink (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area.

* For each head and viscera inspector on cattle slaughter lines a sterilizer

located adjacent to the inspector's work area.

* For mechanized operations, a line control switch adjacent to each inspection station.

* Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands.

* Rail(s) for holding retained carcasses for final disposition along with platforms and handwash sinks. To prevent possible cross contamination, the retain rail must be long enough to prevent carcasses from touching.

20. *Calves, Sheep, and Goats—Chart of Guidelines for Distances for Rails and Other Facilities*

TABLE 4.—GUIDELINES FOR DISTANCES IN CALF, SHEEP, AND GOAT SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance	Horizontal distance
Bleeding rail for calves (distance from top of rail to point of application of shackle to shackled foot—2 feet 6 inches (.8 m)).	11 feet (3.3 m)	
Bleeding rails if only sheep or goats are slaughtered	9 feet—11 feet (2.7 m—3.4 m)	
Dressing rail (trolley length—1 foot (.3 m))	8 feet 6 inches (2.6 m)	
Cooler rails, calf carcasses (trolley length—1 foot (.3 m)).	8 feet 6 inches (2.6 m)	
Cooler rails, sheep or goat carcasses (trolley length—1 foot (.3 m)).	7 feet 6 inches—8 feet 6 inches (2.3 m—2.6 m).	
Moving equipment		
Vertical of rail to edge of viscera inspection stand		2 feet (.6 m)
Length of rail from point of evisceration to point where carcass inspection is completed.		6 feet (1.8 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

Hogs—Additional Facilities Guidelines

In addition to the general guidelines in sections 1 through 8, the following guidelines apply to those establishments that slaughter hogs. Consider these additional guidelines when building or modifying an establishment that slaughters hogs.

21. *Livestock Pens*

* To prevent hogs from overheating, pens for hogs should have either a roof for shelter or a shower system to keep the animals cool in weather with temperatures greater than 70 °F (21 °C).

22. *Location of Certain Operations*

* To prevent contamination, the following equipment and operations should be located in an area or areas separate from the carcass dressing area, except for the openings for access and passage of carcasses:

- ** Hoisting, sticking, and bleeding.
- ** Scalding vat.

** Dehairing machine located within a curbed area having nonclogging drainage outlet.

** Gambrelling table.

** Singeing operations.

23. *Rail Arrangements for Hogs*

The following chart gives guidance for recommended distances for rails and other facilities for hog slaughter operations.

TABLE 5.—GUIDELINES FOR DISTANCES IN HOG SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance
Bleeding rail to sticker's platform.	10 feet 6 inches (3.2 m).
Extension of bleeding rail to top of scalding vat.	9 feet (2.7 m).
Dressing rails ¹	11 feet (3.3 m).
Gambrels (suspending carcasses to floor (1 foot (.3 m)).	10 feet (3 m).

TABLE 5.—GUIDELINES FOR DISTANCES IN HOG SLAUGHTERING ESTABLISHMENTS—Continued

Item	Vertical distance
Distances from rail to bottom of inspection pans and various foot platforms.	
Rails in coolers for hog carcasses with heads removed (1 foot (.3 m)).	9 feet (2.7 m).
Rails to coolers for carcasses with heads attached (1 foot (3 m)).	10 feet (3 m).
Vertical of dressing rail to various foot platforms and widths of platforms.	

¹ Heads dropped but still attached.

Note.—When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

24. *Scalding*

To avoid contamination of the carcass, a scalding tank is used to remove hair and other contaminants.

Consider the following when installing a scalding tank:

- * A mechanical exhaust fan above the scalding tank will disperse steam.

25. Shaving, Singeing, and Carcass Washing

- * A shaving rail (throw-out rail) should be provided prior to the head dropping operation, so that unclean hogs can be removed from the dressing line for cleaning.

- * If a singer is used to remove hair, it should have an automatic cut off and starter switch to prevent the carcass from burning when the chain stops.

- * If a polisher is used, water sprays to clean the carcass of hair should be provided.

- * To remove hair from the hide which was missed by the scald and dehairing process, a carcass washer should be located at a point after completion of shaving operations and before the head dropper's station.

26. Inspection Facilities

Special facilities are needed for USDA post-mortem inspection for swine. Consider the following guidelines when designing these stations:

- * An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector must be provided.

- * When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.

- * A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass must be provided.

- * A handwash sink (other than one which is hand operated), furnished with soap, towels, and hot and cold water, must be provided adjacent to the inspector's work area.

- * For each head inspector on swine slaughter lines, a sterilizer must be located adjacent to the inspector's work area.

- * For mechanized operations, a line control switch must be provided adjacent to each inspection station.

- * For swine slaughter lines requiring three or more inspectors, and for those one-and two-inspector configurations where the establishment installs a mirror, special facilities are needed. At the carcass inspection station one glass or plastic, distortion-free mirror, at least five by five feet (1.5 by 1.5 m), must be mounted at the carcass inspection station. The mirror should be mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet (90 cm) away, to allow any inspector standing at

the carcass inspection station to readily view the back of the carcass.

- * Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands must be provided.

Equines—Additional Facilities

In addition to the general guidelines in sections 1 through 8, and the guidelines for cattle in sections 9–19, if you plan to slaughter equines, such as horses, mules, donkeys, and ponies, the following are additional guidelines when building or modifying equine slaughter facilities.

27. Equine Slaughter Facilities

- * The facilities for equine slaughter establishments are essentially the same as those for slaughtering cattle. Exceptions include the following rail heights and clearances.

TABLE 6.—GUIDELINES FOR DISTANCES IN EQUINE SLAUGHTERING ESTABLISHMENTS

Items	Vertical distance	Horizontal distance
Bleeding rail	18 feet (5.5 m)	
Dressing rails (trolley length—1 foot 3 inches (.4 m)).	12 feet 6 inches (3.8 m)	
Cooler rails (trolley length—1 foot 3 inches (.4 m)).	12 feet 6 inches (3.8 m)	
Cooler rails for carcasses in quarters.	8 feet 6 inches (2.6 m)	
Line of drop-offs to line of half hoists.		17 feet (5.2 m)
Clearance between walls, posts, etc. and adjoining rails in slaughter rooms and coolers.		3 feet (.9 m)
Curb of bleeding area to pritch plates.		6 feet (1.8 m)
Dry landing area (minimum).		7 by 8 feet (2.1 by 2.5 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

**Chapter 10
POULTRY SLAUGHTER ESTABLISHMENTS**

Although the flesh of healthy living poultry is practically sterile, when the bird is killed many factors can contribute to contamination of the carcass including improperly designed

and constructed slaughter facilities. This chapter provides guidelines for facilities for poultry slaughter establishments for you to consider in building or modifying your slaughter facilities. If you slaughter small animals such as rabbits or migratory fowl under voluntary inspection, use this chapter for guidance. See Chapters 1 through 8 for general information which applies to all official meat and poultry establishments.

1. Holding Sheds or Coops

When building holding sheds or coops for poultry, consider the following guidelines:

- * A minimum of 30 foot candles of lighting must be provided to facilitate ante-mortem inspection.

- * The holding sheds should be weather tight.

2. Docks for Receiving and Hanging Live Poultry

Consider the following guidelines to prevent dust, feathers, and other obnoxious substances from entering areas where edible products are being prepared, handled, or stored:

- * The live hanging dock needs to be physically separated from these areas. The separation should be accomplished by full height impervious walls with self-closing impervious doors, and openings limited to that necessary for poultry conveyor systems.

3. Slaughter Area

Consider the following guidelines for the slaughter area to minimize risk of contamination to products:

- * The slaughter area (including stunning, bleeding, picking, scalding, and eviscerating operations) should be separated from those areas of the establishment where edible products are prepared or stored to minimize the risk of contamination.

- * The blood in the slaughtering area, especially the stunning and bleeding area, should be contained in as small an area as possible.

4. USDA Post-Mortem Inspection Station

There are four systems of post-mortem inspection: Traditional Inspection, the Streamlined Inspection System, the New Line Speed Inspection System, and the New Turkey Inspection System. Each of the systems has mandatory requirements to minimize the risk of contamination to products and to promote efficient inspection. However, with the exception of the lighting requirements, there are no facilities guidelines for these post-mortem systems.

5. Facility Guidelines for Poultry Inspection Stations

Note: There are no facility guidelines for Traditional Inspection System facilities except for lighting.

TABLE 7.—FACILITY GUIDELINES FOR POULTRY INSPECTION STATIONS

Facility	SIS	NELS	NTI
The conveyor line should be level for the entire length of the inspection station	X	X	X
The vertical distance from the bottom of the shackles to the top of the adjustable inspection platform, when it is set in its lowest position, should be a minimum of 60 inches (150 cm)	X	X	X
There should be a minimum of 8 feet (2.5 m) of space along the conveyor line for one inspection station and 16 feet (4.9 m) for two inspection stations	X		X
There should be a minimum of 42 feet (12.8 m) of space along the conveyor line for three inspection stations		X	
There should be a minimum of 6 feet (1.8 m) of space along the conveyor line for the establishment employee presenting the birds		X	
There should be a minimum of 4 feet (1.2 m) of space for inspector and a minimum of 4 feet (1.2 m) of space for the establishment helper along the conveyor line	X	X	X
There should be selectors or “kick-outs” with birds on shackles with 12 inch (30 cm) centers (two inspection stations on line)	X		
There should be selectors or “kick-outs” with birds on shackles with 18 inch (45 cm) centers (three inspection stations on line)		X	
A distortion-free mirror should be located at each inspection station which is: at least 3 feet (.9 m) wide and 2 feet (.6 m) high; adjustable between 5 inches (12.5 cm) and 15 inches (38 cm) behind the shackles; positioned in relation to the inspection platform so that the inspector is positioned opposite it 8 to 12 inches (20.3 cm to 30.5 cm) from the downstream edge; installed so that guide bars do not extend in front of the inspection mirror; and illuminated by a light which is positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surface ...		X	
There should be a slip-resistant inspection platform with a 42 inch (105 cm) high rail on the back side and with 1/2 inch (4 cm) foot bumpers on both sides and front	X	X	X
There should be an inspection platform with a minimum length of 4 feet (1.2 m) and minimum width of 2 feet (.6 m)	X	X	X
There should be an adjustable inspection platform that easily and rapidly adjusts a minimum of 14 inches (35 cm) vertically while standing	X	X	X
A trough or other facilities extending beneath the conveyor where processing operations are conducted from carcass opening to trimming should be provided which is wide enough to prevent trimmings, drippings, and other debris from accumulation on the floor or platform; and has enough clearance between suspended carcasses and the trough to prevent contamination of carcasses by splash	X	X	X
A conveyor line stop/start switch should be provided at each inspection station within easy reach of the inspector	X	X	X
A minimum of 200-foot candles of shadow-free lighting with minimum CRI value of 85, which can be met by deluxe cool fluorescent lighting, must be provided	X	X	X
Online hand rinsing facilities with continuous flow water withineasy reach should be provided for each inspector and establishment helper	X	X	X
Online hand rinsing facilities with continuous flow water within easy reach must be provided for each establishment presenter		X	
Receptacles for condemned carcasses and parts should be provided at each inspection station	X	X	X
Hang-back racks should be provided and located within easy reach for establishment helpers	X	X	X

6. Facility Guidelines for Poultry Reinspection Stations

Note: There are no guidelines for Traditional Inspection System facilities except for lighting.

TABLE 8.—FACILITY GUIDELINES FOR POULTRY REINSPECTION STATIONS

Facility	Prechill and postchill reinspection stations	Reinspection stations	
	SIS	NELS	NTI
There should be a minimum of 6 feet (1.8 m) of space along the conveyor line for the establishment presenter		X	
There should be a minimum of 3 feet (.9 m) of space along each conveyor line and for SIS after each chiller	X		X

TABLE 8.—FACILITY GUIDELINES FOR POULTRY REINSPECTION STATIONS—Continued

Facility	Prechill and postchill re-inspection stations	Reinspection stations	
	SIS	NELS	NTI
		A table for reinspecting sample birds should be provided which is at least 2 feet (.6 m) wide, 2 feet (.6 m) deep, and 3 feet (.9 m) high; readily cleanable; and drainable	X
A table for reinspecting sample birds should be provided which is at least 3 feet (.9 m) wide and 2 feet (.6 m) deep; readily cleanable; and drainable		X	X
A space which is level and protected from all traffic and overhead obstructions should be provided ...	X	X	X
The vertical distance from the bottom of the shackles to floor needs to be a minimum of 48 inches (120 cm) should be provided	X	X	X
A minimum of 200-foot candles of shadow-free lighting with a minimum CRI of 85 at the table surface, which can be met by deluxe cool white fluorescent lighting, must be provided	X	X	X
A separate clipboard holder for holding the recording sheets should be provided	X	X	X
Handwash sinks within easy access of all persons working at the station should be provided	X	X	X
Hang-back racks should be provided which are within easy reach of all persons working at the station, and designed to hold 10 carcasses	X	X	X

7. Evisceration and Reprocessing Areas

The evisceration area should be arranged to facilitate efficient sanitary operations and inspection. Consider the following guidelines when designing these areas:

- * Production lines should have drip pans installed beneath them, when these lines are located above areas such as walkways, truckways, work stations, and equipment, to prevent water, poultry products, or any other material from falling on the production areas below.

- * An area should be provided for a reprocessing station for the reconditioning of retained products including removal of contamination.

8. Inedible Offal

In poultry establishments, the facilities for handling inedible offal should be designed to accommodate the size of the poultry being handled and to prevent the contamination of edible products. Consider the following guidelines when designing these areas:

- * The facilities, whether troughs or otherwise, should be large enough to allow clean and orderly removal of inedible offal during processing, without a pile up and without cross contamination of edible products.

- * The water rail for semi-dry poultry offal systems for young chickens should range from 34 to 36 inches (86 to 90 cm) in height above the standing surface and be positioned 7 to 10 inches (18 to 26 cm) horizontally from the vertical line of the shackle.

- * The water rail for semi-dry poultry offal systems for turkeys should range from 34 to 36 inches (86 to 90 cm) in height above the standing surface and be positioned 13 to 15 inches (33 to 38 cm) horizontally from the vertical line of the shackle.

- * The floor gutter should be distinct, with vertical sides inside the post supporting the water rail (a minimum of 6 inches or 15 cm is suggested to prevent workers feet from being in the gutter). Gutters should also be wide enough to catch all material dropping from the carcass.

- * Splash protectors should be installed at all points along the evisceration line where splashing of employees might occur.

- * Pipes for conveying offal should be constructed to permit daily cleaning and positioned so that sanitation will not be a problem, i.e., no pipes lying on the floor or bottom of a gutter.

- * Side walls of hoppers should be pitched to assure that material deposited in the hopper will slide to the point where the offal is being mechanically conveyed.

Chapter 11

PLANT WASTE DISPOSAL

Control and disposal of plant wastes are major concerns. Optimum use and reduction of waste are essential goals of economic production in all plants. From a plant sanitation standpoint, there are two vital concerns with waste disposal: (1) Plant waste contains most of the contaminants and disease-producing and product-spoiling microorganisms from the plant production processes; (2) plant wastes attract pests such as insects and rodents.

1. Organic Waste Disposal

When disposing of organic wastes such as feathers, viscera, blood, and manure, the following guidelines should be considered:

- * Waste materials should not be allowed to accumulate on or near the premises.

- * Waste should be disposed of without creating insanitary or objectionable conditions.

- * Waste should be removed daily.

- * Holding bins should be cleaned before reuse and protected from insect and rodent harborage and infestations.

2. Rubbish Removal

Rubbish, such as paper towels, cartons, office waste, and labeling materials, can become a sanitation problem. The following guidelines should be followed when removing rubbish:

- * Suitable containers should be conveniently located throughout the plant and emptied frequently.

- * The accumulation of rubbish before its removal should not cause a nuisance.

- * Plant refuse should be removed daily, or more often if necessary, to prevent a nuisance.

Appendix B—Guidelines for Developing Partial Quality Control Programs (PQC's)

Guidelines for Developing Partial Quality Control Programs Overview

Quality control programs are essential to the proper functioning of any meat or poultry processing establishment. Processors have found quality control is good business because it can reduce costs, control product uniformity, and ensure that proper standards are being maintained throughout the production cycle. By increasing controls over raw ingredients, processes, and other variables, effective quality control systems can ensure compliance with company specifications and with the guidelines and requirements of the Department of Agriculture. Although in-plant inspectors have a role in the oversight of these programs, quality control is a management function and plant management should develop and implement effective quality control plans specific to their process and products.

There are many approaches plants can take to ensure quality control. Some plants do not take any special measures during production, and changes are made only on finished product. Some plants incorporate preventive measures, such as product testing, during processing, and others undertake a series of specific actions to prevent mistakes and to ensure that products meet consumer expectations. Whether

limited or comprehensive, a quality control system should be in the written record of the plant. As experience is gained, the record keeping system may be improved by focusing on "hot spots" which are responsible for the major problems, revising specifications, or upgrading them to include sensitive testing devices, for example.

Proper documentation of plant activities will become increasingly important in a HACCP inspection environment. Proper documentation of any in-plant process can save time and money and result in fewer mistakes by the establishment. The degree and complexity of the records depend on the scope of the processing operation; completeness of the records is also a reflection of management commitment to quality control.

Plant or corporate management support is the key to a successful quality control program. Plant personnel will sense a lack of commitment to quality if management support is not apparent.

Good quality control managers do not necessarily have to use complex, expensive methods to ensure control. Experience has shown that successful establishments function smoothly by paying close attention to the basics, documenting the process when it is running smoothly and when problems occur, and making necessary corrections as quickly as possible.

Chapter 1. Introduction

Title 9 of the Code of Federal Regulations at Parts 318.4(d) and 381.145(d) require Federal meat and poultry processing plants to establish and maintain written records for each critical check or critical control point and make the records available to FSIS inspection personnel upon request.

* Although the regulatory requirement for FSIS to review and approve PQC programs has been rescinded, the new regulatory requirements in 318.4(d) and 381.145(d) provide information to plants about the necessary steps they must take to meet the new record keeping requirements in a Pathogen Reduction and HACCP inspection environment.

* FSIS will continue to provide guidance to establishments to ensure that their Partial Quality Control (PQC) programs for specific products and processes are adequate to ensure product compliance with regulatory requirements. The information in this document is intended to be used as guidance material and is based on FSIS' experience and historical perspective reviewing and approving PQC programs.

A few model PQC programs, representative of many products and processes, are presented below.

Chapter 2. Components of PQC Programs

PQC programs should address four areas: (1) raw materials control; (2) process control; (3) records control; and (4) corrective/preventive action.

1. Raw Materials Control

Raw materials control involves the receiving and stocking of only those materials that conform to established specifications. To ensure successful control of raw materials, establishments should consider the following:

* To begin the development of a raw materials control procedure, plants should list each of the materials used to produce the product.

* Once the list has been created, establishments should develop a receiving inspection procedure.

* The procedure may address raw materials specifications, proper materials handling, proper storage, and disposal of nonconforming materials.

* Materials should be routinely monitored to ensure they are meeting the established procedures.

2. Process Control

Process control programs ensure continuous control of particular processes so that product standards will be met. Process control programs should meet the following criteria:

* They should identify the products or processes to be controlled.

* They should identify the control features necessary for product compliance.

* They should establish control limits.

* They should establish procedures for meeting the established limits.

* They should provide monitoring procedures for ensuring that procedures are followed.

An important aspect of process control is effective data collection and analysis. Process control programs should include sampling plans that permit reliable collection and analysis of data. After sampling plans have been developed, process limits can be established.

* The limits established should be appropriate to ensure that quality standards will be met.

* The limits established should be appropriate to ensure that meet regulatory or label limits for the product or process will be met.

* Variation in materials, methods, processes, and products requires the setting of a tolerance for each quality

standard. A tolerance limit is the total allowable deviation from an established standard. The limit allows for the normal variability which is inherent in any process.

* Tolerance limits may need to be continuously adjusted to prevent problems.

* Limits for certain processes have been established and used historically by industry; these limits are reflected in PQC programs previously approved by FSIS. The tolerances meet the intent of the requirements in 318.4(d) and 318.145(d)(2)(ii) and may continue to be used.

* Establishments may elect to use these previously established tolerances or develop their own by following the requirements outlined in the regulation.

3. Records

An important aspect of quality control is process documentation. Adequate records are essential to the system's capacity to provide the necessary controls. The records provide a history of the process and document when the process is working and when problems are occurring. The use of standard sheets, check-off forms, and other simple records is generally more successful than a complicated system. Charts and graphs already in use may be all that is necessary to document the system. The degree of record keeping and the complexity of the records depend, in large part, on the scope of the processing operation. In reviewing records, plant management should:

* Look at those aspects of production most likely to cause problems. This procedure also can be useful in determining what critical checks need to be incorporated into a quality control program.

* Correct problems as they occur. Proper documentation of the process can save time and money because it provides an establishment an opportunity to correct a problem before the finished product has been completed.

4. Corrective/Preventive Action

Corrective action plans address the action to be taken when problems develop in a production process. Corrective action plans are essential components and important indicators of the strength of quality control programs. The primary emphasis of the plans should be on correction/prevention of problems in the production process. The type of plan used in a particular quality control program will be determined by the establishment and the processes conducted at the plant. Generally,

corrective action plans should include the following features:

- * They should provide for the identification of problems or deviations in processes.
- * They should provide for the identification of the causes of problems.
- * They should specify the corrective steps to be initiated and the criteria for determining how noncompliant products should be handled.
- * The plans should provide that corrective/preventive measures be implemented after a determination that no safety hazards exist.
- * The plans should provide for documentation of the corrective and preventive measures taken.

Models

The following models are intended to be used as general guidelines to developers of quality control programs. They are not intended to be complete QC programs or a complete listing of all rotational QC programs but offer a framework and one approach to QC program development. In actual QC programs, details regarding tests, action criteria, corrective actions, and responsible personnel would reflect the specific process and establishment circumstances. Any specifications or limits cited are only examples and do not establish or imply Agency standards.

Model 1—Preparation of a PQC Program for the Addition of 10-Percent Solution to Poultry

Raw Material Control

* Poultry—Chicken breasts will be received frozen, examined for condition, and immediately placed in the receiving dock freezer. (Specifications to be set by establishment.)

* Dry ingredients—Upon receipt, the dry ingredients will be visually inspected for acceptance and immediately placed in the dry storage warehouse. (Specifications to be set by establishment.)

* Corrective action—If either the poultry or the dry ingredients is found to be unacceptable, it will be tagged immediately and Quality Control will be notified. QC will evaluate and initiate appropriate product disposition.

* Documentation—All critical checks and corrective actions will be recorded on the receiving log.

Process Control

* Formulation control.
 ** Formulation control—A pumping solution will be formulated according to the label formulation. One ingredient of the solution will be weighed by a quality control technician for each

batch. If an ingredient is found to be more than 0.5 percent above or below the weight stated on the formula, the following will result: (1) the problem will be evaluated and the appropriate corrective action taken; (2) each ingredient of every batch will be checked until five consecutive batches are found to be in compliance.

** Documentation—All formulation check results and corrective actions, if needed, will be recorded on the formulation log.

** Scale accuracy control.

*** Scale checks—All scales associated with the pumping operation will be verified for accuracy before operations begin. Scale accuracy will be checked against a known weight. If a scale is found to be inaccurate, it will not be used until it has been calibrated.

*** Documentation—All scale check results and corrective actions, if required, will be recorded on the scale maintenance record.

Lotting

* A lot will be defined as one shift's production; a subplot as approximately 500 pounds of product.

Added Solutions

* Green weight determination—Each subplot will be identified with a unique code representing date and time of day the subplot is being produced.

** The subplot will be weighed before pumping.

** The identifying code and weight will be written on a tag, which will be attached to the combo bin containing the subplot.

* Pumping—Every 30 minutes, 10 turkey breasts will be selected from a subplot before it is pumped. The 10 turkey breasts will be weighed, then passed through the pumping machine. The turkey breasts will be allowed to drain for 5 minutes, then weighed again.

** Tolerances—Each pump check will not be more than 0.5 percent over the target pump of 10 percent. If a pump check is found to exceed the tolerance, all product back the last pump check will be retained and allowed to drain until it reaches the target pump. In addition, the pumping operations will be stopped, evaluated by a QC technician, and not allowed to start until the problem has been corrected.

** Documentation—All pump checks and corrective actions, if needed, will be documented in the pumping log book.

* Finished weight determination—After a subplot has been pumped, a final weight will be obtained and recorded on the pumping tag.

** Tolerances—No subplot will be more than 1.2 percent above the target

pump of 10 percent. The average of all sublots will meet the target pump. If any subplot or the average of the sublots exceeds tolerances, all product will be retained and allowed to drain until the target pump has been reached.

** Documentation—All green weights, finished product weights, and corrective actions, if needed, will be recorded in the finished product log book.

Note: Model also can be used in developing the following PQC programs:

Percent Labeling Control
 Water-misted/Ice-glazed Meat and Poultry Products
 Addition of Solution to Raw/Cooked Meat and Poultry Products (Injection, Massaging, Tumbling, Basting, Marination, and Tenderization)
 Fat and/or added water for Raw Product

Model 2. Preparation of a PQC Program for Fat-Content-per-Serving Labeling for Meat and Non-Meat Products

Scales/Meters

* Establish verification procedures to ensure that all scales/meters used in the formulation and analytical testing of the product are accurate. The procedure should include checks against a standard weight or measurement.

Lotting

* Define lot and subplot.
 * Establish a standardized procedure for identifying the lot throughout the process.

Formulation

* Establish a procedure to verify the formulation of each lot/sublot in compliance with the approved label formulation.

* Establish tolerances for non-restricted ingredients.

* No ingredient in the formulation should be substituted for another. Fat content of the meat portion (ground beef, ground pork, or products with a declared fat limit on the label)

* Establish a statistically sound sampling procedure for each lot/sublot of the meat portion.

* Identify the analytical method used, such as an AOAC method. Weight Control (serving and component).

* Establish a statistically sound sampling procedure to ensure that each portion and component of the product within a lot/sublot is checked against the label transmitted.

* Raw weights—The weight is checked on all portions and components on finished raw and cooked products.

* Cooked weights—Cooked weights are checked and compared with the portion size stated on the transmittal

and on the Child Nutrition (CN) label. Weights also are checked for precooked components of products against information on the label transmittal.

* The sampling plans and tolerances should be based on generally recognized statistical process control methods and should ensure that the process is in control and that applicable product or label limits are being met.

* Each CN product should have its own lot average.

Batter and Breading (if applicable)

* Establish a procedure to verify that the batter/breading application does not exceed regulatory limits, label declarations, or product standards. The monitoring procedure should identify the following:

** pre-batter/breading application weight

** sample size

** sample frequency

** post-batter/breading application weight

* Post-batter/breading weight should be determined at the end of the application procedure and before further processing. Note: Model also can be used in developing the following PQC programs:

Batter and Breading

FES Labeling Content for Meat and Non-Meat Products

Precooked Breakfast Sausage Yield Control

Model 3. Low Temperature Rendering for the Production of Partially Defatted Chopped (P.C.) Beef/Pork, Fat-Reduced Species, and Partially Defatted Beef/Pork Fatty Tissue

Raw Materials Control

* Define a lot and subplot

* If producing P.C. beef/pork or fat-reduced species, establish a statistically based sampling procedure to ensure the lot is in compliance with raw material requirements (12 percent lean).

Heat Processing

* Identify processing temperature (minimum and maximum).

* Identify the target processing time, which is the time the product is subjected to the target.

* Establish procedures for monitoring processing temperatures and times.

Cooling and Freezing Controls

* Identify the cooling and freezing temperatures for the finished product.

* Identify the amount of time the cooling and freezing process will take to reach established temperatures.

Microbiological

* If the cooling/freezing process (starting from the time heat is applied until the product is 40 degrees F for less) exceeds 30 minutes, a microbiological sampling procedure should be developed. The following sampling procedures and limits have been used in PQC programs in the past, and current regulations permit their continued use.

** Using a statistically based sampling plan, select two samples per lot from the raw material and finished products.

** Test samples for total plate count, coliforms, *E. coli*, and *C. Perfringens*.

** Demonstrate that the process does not increase the product's microbial load by 1 log or more.

** Sampling can be reduced to one per lot when control has been demonstrated in three consecutive lots.

Finished Product Controls

* If producing finely textured lean or finely textured extra lean, product should be tested for fat, protein, and protein efficiency ratio (PER) or essential amino acid (EAA).

* Incorporate the sampling procedure for fat and protein.

** Individual—Obtain a one-pound sample from each lot. After 10 consecutive analyses are in compliance with single sample limits, sampling may be reduced to one randomly sampled lot out of every three lots.

** Process Average—A process (moving) average of 10 lots should be maintained.

Sampling Procedures for PER/EAA

* Initially, each lot should be held and tested until compliance has been established. Once compliance has been established in three consecutive lots, sampling may be reduced. Sampling frequency should begin with at least one sample per month until compliance has been established. When three consecutive samples are in compliance, the frequency may be reduced to one sample every three months.

* Analytical Standard Limits

Finely Textured Lean Product

Individual:

Fat—Maximum 30%

Protein—Minimum 13%

Process Average:

Fat—Maximum 30%

Protein—Minimum 14%

PER 2.5 or

EAA 33%

Finely Textured Extra Lean Similar Products

Individual:

Fat—Maximum 11%

Protein—Minimum 13%

Process Average:

Fat—Maximum 10%

Protein—Minimum 14%

PER 2.5 or

EAA 33%

Corrective and Preventive Actions

* Develop corrective and preventive actions for each critical check point established.

Note: Model also can be used in developing the following PQC programs:

Low Temperature Rendering for Control of Partially Defatted Chopped Beef/Pork Fat-Reduced Species and Partially Defatted Beef/Pork Fatty Tissue

[FR Doc. 97-21882 Filed 8-22-97; 8:45 am]

BILLING CODE 3410-DM-P