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**Regulations Governing the Certification of
Sanitary Design and Fabrication of
Equipment Used in the Processing of
Livestock and Poultry Products; Final
Rule**

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 54**

[Docket No. LS-98-09]

RIN 0581-AB69

Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Processing of Livestock and Poultry Products**AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) has developed a voluntary, user-fee-funded program under the provisions of the Agricultural Marketing Act of 1946 to inspect and certify equipment and utensils used to process livestock and poultry products. Livestock and poultry processing equipment and utensils inspected and certified by AMS to voluntary consensus standards for sanitary design will provide a third party assurance that they meet minimum requirements for cleanability, suitability of materials used in construction, durability and inspectability.

EFFECTIVE DATE: January 8, 2001.**FOR FURTHER INFORMATION CONTACT:**

Barry Carpenter, Deputy Administrator, Livestock and Seed Program, by telephone at (202) 720-5705 or by Fax at (202) 720-3499.

SUPPLEMENTARY INFORMATION: The information that follows has been divided into three sections. The first one provides background information including a summary of the history of this rulemaking process. The second section provides a summary of the comments received in response to the proposed rule published in the **Federal Register** on June 6, 2000, and the Agency's responses to these comments including changes made in this final rule as a result of the comments. The last section provides the impact analysis section that addresses various requirements including the Regulatory Flexibility Act, the Paperwork Reduction Act, Civil Rights Review, and the relevant Executive Orders.

I. Background

Provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106-387, sec. 729) require AMS to develop a voluntary, user-fee-funded program to inspect and certify equipment and

utensils used to process livestock and poultry products. Prior to this amendment, similar language appeared in appropriations acts for fiscal year 1999 (Pub. L. 105-277, sec. 747) and fiscal year 2000 (Pub. L. 106-78, sec. 734). The program will be conducted under the provisions of the Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621 *et seq.*). From 1975 to 1997, a similar function was carried out by USDA on a mandatory prior approval basis by USDA's Food Safety and Inspection Service (FSIS) as a prerequisite for equipment use in federally inspected meat and poultry packing and processing establishments. The FSIS Equipment Branch formally evaluated equipment and utensils proposed by manufacturers or suppliers before they could be used in official establishments to assure they could be maintained in a sanitary condition. The program focused on identifying and correcting problems during the initial development of equipment and utensils.

FSIS's acceptance of new, modified, or reconditioned equipment and utensils for use in federally inspected meat and poultry establishments was a two-step process. First, FSIS Equipment Branch personnel evaluated the design and construction of equipment by reviewing assembly-type drawings and corresponding parts and material lists submitted to the Branch by the equipment manufacturer. Then, if necessary, FSIS inspectors reviewed the in-establishment operation of the equipment and reported their findings to the Equipment Branch. Commercially available equipment was accepted and listed in an FSIS reference guide, "Accepted Meat and Poultry Equipment." Once equipment was listed in this reference as acceptable, no further approval was needed on an establishment basis.

FSIS continues to ensure that equipment and utensils used in federally inspected facilities are of such material and construction as will facilitate their thorough cleaning and operational cleanliness, and not adulterate edible product. Also, FSIS still requires that equipment and utensils used in federally inspected establishments are constructed, maintained, and used in a manner that does not interfere with inspection. However, in an effort to remove "command and control" regulations that were contrary to FSIS' commitment to the Hazard Analysis and Critical Control Point approach to Federal meat inspection, and to provide federally inspected establishments with the flexibility to use equipment and utensils designed in the manner they deem to

best maintain a sanitary environment for food production without having to seek prior approval, FSIS discontinued the mandatory prior approval program for equipment and utensils on September 24, 1997 (62 FR 45016).

At the time FSIS announced that it was discontinuing its prior approval program, equipment and utensil manufacturers and processors of livestock and poultry products expressed their desire to either continue the FSIS program or develop a new program through AMS on a voluntary, user-fee-funded basis to inspect and certify equipment and utensils used to process livestock and poultry products to a sanitary standard. Subsequently, provisions of the fiscal year 1999 appropriations required development of such a program by the Secretary of Agriculture under the authority AMA of 1946.

Accordingly, on July 16, 1999, AMS published in the **Federal Register** (64 FR 38315) an advance notice of proposed rulemaking (ANPRM) and notice of public meeting to assist the Agency in the development of a complete inspection and certification program for equipment and utensils used to process livestock and poultry products.

Through the ANPRM and the public meeting, AMS sought information which would enable the Agency to develop an efficient and cost-effective program for inspecting and certifying equipment and utensils used to process livestock and poultry products. Specifically, AMS requested comments concerning: initiatives underway in the industry to develop a voluntary, consensus sanitary standard for the design and manufacture of equipment and utensils used to process livestock and poultry products; the validity and usability of standards presented to AMS for consideration for adoption; criteria to be used by AMS to select a sanitary standard; and any other information which would aid AMS in administering the program.

The ANPRM solicited comments on the issue for a 60-day period ending September 14, 1999. The public meeting was held on August 10, 1999, in Room 107-A at the USDA Jamie L. Whitten Building, 12th and Jefferson Drive, SW., Washington, DC.

To assist interested parties in obtaining information on the proposed program and in reviewing comments as AMS received them, the Agency launched a website at www.ams.usda.gov/lsg/equip.htm. Contained on this website were electronic versions of the AMS press releases related to the development of

the program, the ANPRM, complete transcripts of the August 10, 1999, public meeting, and all comments received.

The public meeting was attended by 42 representatives of the meat and poultry packing and processing industry, equipment and utensil manufacturing industry, trade and professional associations, standards developers, and other interested parties. Twelve individuals provided prepared remarks at the meeting. AMS received 51 comments during the comment period for the ANPRM.

On June 6, 2000, AMS published in the **Federal Register** (65 FR 35857), a proposed rule which responded to the ANPRM comments and solicited additional public comment. AMS received 100 comments during the comment period which ended August 7, 2000. The regulatory text of this final rule incorporates changes made in response to these comments and upon further review by AMS.

II. Comments and Responses

General Program Comments

Support for Program

Summary of Comments: Forty-one commenters expressed general support of the development of the program as presented in the proposed rule which included the standards developed by the NSF/3-A Joint Committee on Food Processing Equipment, the voluntary aspects of the service, and the use of Federal employees to provide the service. Thirty-three of these commenters specifically supported AMS as the certifying agency.

Agency Response: AMS has considered these comments in support of the program as it has contemplated changes from the proposed rule to this final rule.

Program Would Become Mandatory Requirement

Summary of Comments: Three commenters expressed concern that this program would become a "de-facto" mandatory requirement and that AMS should clearly state in the final rule that equipment manufacturers remain free to obtain other third party certifications or can "self-certify" that equipment is sanitarily designed and manufactured.

Agency Response: Throughout the development of these regulations and this program, AMS has maintained that the service to be implemented is voluntary and user-fee-funded. Accordingly, no equipment fabricator or user is required to participate in this program. Private certification providers can propose and offer other services to

the livestock and poultry industries without restriction by these regulations. Therefore, equipment fabricators and users may use whatever means they desire, including "self certification", as suggested by commenters, to market or represent their products.

Comments Referring to AMS Providing the Inspection and Certification Service Competition With the Private Sector

Summary of Comments: Five commenters generally opposed AMS providing the certification service because of concerns over public-private competition. One commenter also asserted that the Office of Management and Budget (OMB), Circular A-76 requires Federal agencies to use private sector services rather than offer duplicative services.

Agency Response: The comments received during the comment periods for the both ANPRM and the proposed rule indicate a clear desire by the livestock and poultry industry that this voluntary certification service be provided by AMS using government employees. These final regulations establish a voluntary, third-party evaluation service administered by AMS which is consistent with other, similar services provided by AMS for the inspection and grading of agricultural products, for laboratory services, for the evaluation of the sanitary design of equipment used in the dairy industry, and for the display of official identification marks. As such, no equipment fabricator or user is required to participate in this AMS service and equipment manufacturers and other users may choose any other voluntary, private certification service available to them. Furthermore, the regulations do not prevent, exclude or limit any private organization from independently offering a certification service of their own design to the livestock and poultry industry. With regard to concerns over the regulation's conformance with OMB Circular A-76, it is our view that this rule is consistent with the provisions of the Circular.

Effect of Program on Private Certification Providers

Summary of Comments: One commenter stated that AMS failed to consider the potential effects of the regulation upon private certification providers.

Agency Response: AMS did consider potential effects upon third parties. The service to be implemented by AMS is voluntary and user-fee-funded. As already stated, no equipment fabricator or user is required to participate in this

program. Private certification providers may offer their services to the livestock and poultry industries without restriction by these regulations. Therefore, equipment fabricators and users may use whatever means they desire to demonstrate that their products are suitable for use.

Reexamine Alternatives to Proposed Program

Summary of Comments: One commenter asked AMS to reexamine alternatives under the agricultural appropriations act considering programs already implemented or publicly contemplated by AMS and offer an accreditation service for conformity assessment organizations in lieu of a certification service.

Agency Response: The Act provides that USDA develop a voluntary, user-fee-funded program to inspect and certify equipment used to process livestock and poultry products. Accordingly, the Agency examined alternatives, including the alternative suggested by the commenter. Additionally, AMS evaluated comments received in response to the ANPRM and the proposed rule as the alternatives were considered. The alternative option to develop a third-party certifier accreditation service was evaluated and rejected by AMS. The statutory language provides that the Secretary inspect and certify agricultural processing equipment. Further, a significant number of comments during the comment periods for the ANPRM and proposed rule which supported an AMS provided service staffed by Federal employees to conduct the evaluations.

Conformance of Program to ISO and ANSI Standards for Third Party Certification Bodies

Summary of Comments: Two commenters stated the proposed program did not conform to ISO or American National Standards Institute (ANSI) provisions or standards for third party certification bodies.

Agency Response: It has never been the objective or intent that the certification service provided by AMS would conform to ISO or ANSI provisions or standards for third party certification bodies. AMS intends to operate this program consistent with other voluntary, user-fee-funded inspection and certification services already provided by the Agency. AMS believes that this decision is consistent with the intent of Congress and the expectation of equipment manufacturers and meat and poultry processors who requested AMS develop the service.

Continued Compliance with NSF/3-A Standards

Summary of Comments: Two commenters stated that the proposed program did not provide for continued compliance with the NSF/3-A Standard and that the regulations need to offer interested parties the opportunity to question the appropriateness of an AMS certification of compliance. Additionally, one commenter asked what would happen to those manufacturers who do not report a change in the design of their equipment to AMS, and how would AMS verify if a change had occurred and was not reported.

Agency Response: After a review of the proposed regulations, AMS believes these comments have merit. Accordingly, § 54.1019 has been modified to require a manufacturer of any equipment or utensil which has been issued a report or certification of compliance to resubmit for evaluation any change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil. Similarly, AMS encourages interested parties to contact AMS if they have any questions regarding the appropriateness of an AMS certification of compliance. AMS can use this feedback as a basis for initiating a review to ensure that equipment marketed as certified through this program comply with the standards.

Recertification of Equipment

Summary of Comments: Seventy-two commenters requested AMS clarify or streamline the process for recertification of equipment. The commenters expressed confusion as to AMS' intent behind the wording used in the proposal stating that recertification by AMS was required after "any" change to the design was made. Commenters generally favored AMS only requiring recertification of equipment when a change of design is made that may affect the hygienic, cleanliness, or sanitary aspects of the equipment.

Agency Response: AMS agrees and has revised § 54.1019 in these regulations to clarify that only changes which impair the cleanability or hygienic design of the equipment or utensil need to be submitted for recertification.

Independent Audits

Summary of Comments: One commenter stated that the program did not provide for independent audits of the manufacturing facility.

Agency Response: The regulations do not provide for such audits as such

audits are not intended to be a part of this service. AMS believes a requirement in these regulations for independent audits of the equipment or utensil manufacturers' facilities is not necessary. The addition of an AMS audit requirement of the manufacturer's facilities would substantially increase the cost of this voluntary program and the Agency believes the marginal benefit of such audits would be unwarranted. Additionally, the FSIS inspection program continues to be responsible for ensuring that equipment and utensils used in federally inspected facilities are of such material and construction as will facilitate their through cleaning and operational cleanliness, and not adulterate edible product. AMS believes the service to be provided by these regulations, particularly those in §§ 54.1019, contain sufficient internal controls to protect the integrity of its evaluations and certifications.

Requiring Samples, Material Lists and On-site Audits

Summary of Comments: One commenter objected to the program not requiring examination of samples, materials lists, or on-site audits. Three additional commenters requested clarification on the issue of when an on-site audit is required.

Agency Response: In order to allow for the greatest flexibility for applicants to apply for this service, AMS does not require blueprints, samples, and materials list be submitted with the application for all pieces of equipment and utensils. However, if sufficient information is unavailable for AMS to accurately evaluate the design of a specific piece of equipment or utensil, which could include the materials used in construction, a report or certification of acceptance will not be granted until such information that is required to perform the inspection is provided.

With respect to on-site audits, the evaluation and certification process includes the fabrication of the equipment or utensil. The only means available to AMS to accurately determine that acceptable fabrication techniques have been accomplished is to evaluate the completed piece of equipment or utensil. Depending upon the size and complexity of the equipment or utensil, this determination can only be accomplished with an on-site evaluation. Once a report or certificate of acceptance has been issued, additional on-site evaluations would be necessary only if the fabricator modified the design and requests a recertification under the provisions of § 54.1019. As appropriate to the review and evaluation process, AMS will

conduct on-site reviews of the actual equipment at the point of fabrication or where installed. Section 54.1014 provide the regulatory language outlining the requirements for accessibility of the equipment for evaluation.

Because AMS believes that blueprints, material lists and on-site audits will be required in virtually every instance envisioned by the Agency, the cost burden estimates for this program put forward in the Impact Analysis section of this rule assume all applicants will submit such documentation and will receive an on-site audit.

Model Lines

Summary of Comments: Ten commenters requested clarification of how AMS would process equipment which is part of a model line. Specifically, they requested clarification as to whether each member of the model line needed to be submitted for evaluation and certification.

Agency Response: AMS agrees that a clarification is needed. Accordingly, § 54.1006 has been modified by adding the wording, "Equipment or utensils having an identical design, materials of construction, and fabrication, except for scaling up or down in size, may be submitted for evaluation as a model line or series."

Four Year Certification Review

Summary of Comments: Three commenters objected to the requirement that certification must be reviewed every 4 years.

Agency Response: AMS disagrees. Based on experience, AMS believes equipment design and fabrication change frequently to meet the demands and needs of the equipment users. Section 54.1019 provides the requirements for these changes to be accommodated within the evaluation and certification process. For those types of equipment or utensil which change infrequently or not at all, the regulations provide for a simple procedure whereby the fabricator can state that no changes in the design or fabrication have occurred. AMS continues to support the need for these provisions as program integrity safeguards that the certifications issued by AMS are valid and that the four year recertification cycle is appropriate for AMS needs while not being overly restrictive to the livestock and poultry industries.

Comments Referring to the Selection of Standards That AMS Will Inspect and Certify Equipment To

Support for Adoption of NSF/3-A Standards

Summary of Comments: Twenty-two commenters supported the adoption of the standards developed by the NSF/3-A Joint Committee on Food Processing Equipment.

Agency Response: AMS has adopted these standards as the basis of this certification program.

Incorporation of NSF/3-A Standards

Summary of Comments: Sixty-nine commenters stated opposition to the way AMS incorporated the NSF/3-A standard in the proposed regulations. Commenters requested any changes to the standards be made through notice and comment in the **Federal Register**. One of the commenters stated AMS failed to follow OMB Circular A-119 made in the proposed rule.

Agency Response: As stated in the proposed rule, AMS will inspect and certify equipment and utensils to standards developed by the NSF/3-A Joint Committee on Food Processing Equipment. NSF is an ANSI *Designated Audited Certifier*. As such, NSF follows all ANSI procedures for standards development and the final published standards will be ANSI/NSF/3-A standards consistent with the provisions of OMB Circular A-119. AMS believes that these ANSI procedures provide for the required participation by all interested parties during all phases of the standards development process to ensure all points of view or concerns are considered before publication of the final standard. However, apart from the ANSI procedures for standards development, AMS encourages public comment on all of its services, and the standards the Agency uses as the basis of its services, including this program. To ensure that public comment is received prior to changes in the standards AMS uses, AMS will provide notice of pending changes in the standards to encourage interested parties to provide AMS with feedback and so they may also comment directly to the NSF/3-A Joint Committee.

Enforcement of the Worker Safety Provisions of the NSF/3-A Standards

Summary of Comments: Seventy-two commenters requested the program not enforce the worker safety provisions of the NSF/3-A standards adopted.

Agency Response: The scope of the NSF/3-A standards apply only to the hygienic requirements of the equipment or utensil design and had not intended

to evaluate or comment on worker or occupational safety issues. Similar comments were also made to the NSF/3-A Joint Committee. In August 2000, the Joint Committee published NSF/3-A 14159-1, Draft 7.0 which included modified wording to delete the references to worker and occupational safety from application to livestock and poultry processing equipment and utensils. In view of the changes to the standards effected by the NSF/3-A Joint Committee, AMS believes the concerns raised by the commenters has been resolved and no additional action is needed by AMS.

Opposition to Use of Draft Standards

Summary of Comments: Two commenters objected to the use of the NSF/3-A standard because it is a draft standard.

Agency Response: At the time of the publication of the proposed rule the NSF/3-A standard was a draft standard, however the final ANSI/NSF/3-A standard has now been published and accepted as an American National Standard.

AMS Proposing One or Many Standards

Summary of Comments: One commenter was confused whether AMS was proposing one standard or many standards.

Agency Response: AMS will inspect and certify equipment and utensils to standards developed by the NSF/3-A Joint Committee on Food Processing Equipment. This Joint Committee will develop a wide-range of standards dealing with the hygienic design of equipment. As already stated, one standard has been completed by the Joint Committee and the committee is in the process of developing additional consensus standards. It is the intent of AMS to inspect and certify equipment and utensils to all standards finalized by the Joint Committee that are appropriate to the livestock and poultry industries. As standards are developed, this may result in the application of multiple standards by AMS to the appropriate pieces of equipment and utensils, as well as to the appropriate segments of the industry.

AMS Should Develop Its Own Standards

Summary of Comments: One commenter stated that they would have preferred that AMS write its own standards.

Agency Response: AMS disagrees. As already stated, AMS will inspect and certify equipment and utensils to standards developed by the NSF/3-A Joint Committee on Food Processing

Equipment. AMS does not believe that the development of a new AMS standards would improve the service or provide users with any benefits.

Use of ISO Standards

Summary of Comments: One commenter recommended that any third party certifier should use International Organization for Standardization (ISO) standards.

Agency Response: The primary purpose of the regulations is to provide a third party certification that equipment meet specified standards. The service developed by AMS is intended to meet the needs expressed by the domestic livestock and poultry industries for a third party evaluation of the sanitary design of processing equipment according to specified standards. However, during development of the service, AMS did evaluate and consider international harmonization and compatibility with appropriate ISO standards. The standards developed by the NSF/3-A Joint Committee on Food Processing Equipment, which will be used by AMS, are based on the corresponding ISO standard, ISO/DIS 14159:1997 Safety of Machinery—Hygiene requirements for the design of machinery.

Representation of Manufacturers in NSF/3-A Standards Development Process

Summary of Comments: Two commenters objected to the use of the NSF/3-A standards because “manufacturers were not represented”.

Agency Response: Equipment manufacturers are represented on the Joint Committee and the technical working groups. Further, the ANSI procedures followed by the Joint Committee for the development of standards requires that all interested parties be included in the development process.

Support for Other Standards

Summary of Comments: One commenter requested AMS adopt the ANSI/UL 2128—Meat and Poultry Plant Equipment Standard developed by the Underwriters Laboratories, Inc., instead of the NSF/3-A standard because the ANSI/UL 2128 standard is the American National Standard.

Agency Response: Since publication of the proposed rule, the NSF/3-A Joint Committee has now finalized their deliberation and published the draft standard that was proposed in final form. Accordingly, the NSF/3-A standard is now an American National Standard.

Suggested Revisions to NSF/3-A Standards

Summary of Comments: Thirteen commenters provided specific revisions that they would like made to the hygienic portions of the NSF/3-A draft standards.

Agency Response: AMS appreciates this feedback and will use it as it evaluates revisions that may need to be made to the NSF/3-A standards. AMS also recommends the commenters direct their specific revision changes to the NSF/3-A Joint Committee, NSF International, P. O. Box 130140, 789 N. Dixboro Rd., Ann Arbor, MI 48105.

As already stated, AMS encourages public comment on all of its services, and the standards the Agency uses as the basis of its services, including this program. To ensure that public comment is received prior to changes in the standards AMS uses, AMS will provide notice of pending changes in the standards to encourage interested parties to provide AMS with feedback and so they may also comment directly to the NSF/3-A Joint Committee.

Comments Referring to Administrative Issues

Grandfathering of Equipment Approved Under the Former FSIS Program

Summary of Comments: Two commenters requested that equipment approved under the former FSIS prior-approval program be "grandfathered" under this program.

Agency Response: AMS disagrees. The standards applicable under the two programs are different. It would be inappropriate for AMS to "grandfather" equipment that did not meet the standards proposed under this service that would then compete in the market place with equipment fabricators complying with the new standards.

AMS Work With Industry Associations

Summary of Comments: One commenter requested we inform the industry associations about what we are doing.

Agency Response: AMS agrees. AMS has participated in a number of informational meetings with all of the major industry trade associations whose members use AMS programs and services.

Keep Program Simple and Straightforward

Summary of Comments: One commenter requested we keep the program as "simple and straightforward" as possible.

Agency Response: AMS agrees. It is the goal of AMS in these regulations to

provide a voluntary, user-fee-funded evaluation and certification program that meets the needs of the livestock and poultry industries, and is carried out in a manner as simple, straightforward, efficiently and cost effective as possible.

Marketing Claims

Summary of Comments: Nine commenters expressed concern over language in the proposed rule restricting the use of marketing claims on promotional literature for equipment not approved by this program.

Additionally, commenters requested that approval letters from the former FSIS prior-approval program be allowed to be used and that such equipment be allowed to be marketed with the claim "USDA accepted equipment" and "USDA approved."

Agency Response: AMS disagrees. The standards and procedures provided for in these regulations are different than those implemented by the FSIS prior-approval program. As such, it would be unfair to participants in the this new program to have to compete with claims of manufacturers sanctioned under the former FSIS program which have not participated in this new AMS service. FSIS discontinued the mandatory prior approval program for equipment and utensils on September 24, 1997 (62 FR 45016). Since that time, there has been no procedure available to assure that the equipment or utensils covered by letters issued during the former FSIS program accurately represent the current equipment design or that such equipment even still meet current FSIS requirements.

Program Budgeting and Appropriations by Congress

Summary of Comments: One commenter stated their belief that the new service would be subject to congressional budgeting and appropriations.

Agency Response: The commenter is not correct. This service is fully user-fee supported.

AMS Staffing Levels and Certification Turnaround Times

Summary of Comments: Four commenters expressed concern over AMS staffing levels and turnaround times on certifications. Two of the commenters specifically asked that AMS include a maximum certification turnaround time in the regulations (30 and 60 days).

Agency Response: AMS will staff the program with sufficient personnel to accomplish the goals of the program using the best estimates available to

AMS while still operating the program in an efficient and cost effective manner. AMS disagrees with the suggestion of commenters to include a maximum turnaround time in the regulations. Due to the complexity and sophistication of many of the designs eligible for evaluation and certification, turnaround time restrictions could be unrealistic and ultimately detrimental to the evaluation process.

Rejections of Applications

Summary of Comments: One commenter objected to AMS being able to reject an application based on "administrative reasons such as the non-availability of personnel to perform the service."

Agency Response: AMS disagrees. While AMS intends to provide service to applicants consistent with this subpart, there may be instances where such service may not be provided. Accordingly, the provision will remain unchanged.

Acceptance of Program by FSIS

Summary of Comments: One commenter requested AMS work to ensure this program is accepted by FSIS.

Agency Response: AMS has worked to ensure FSIS is fully aware of the services being developed by AMS. Additionally, AMS has informed FSIS of our availability to provide information about this service to their management or employees.

Third-party Appeal of Certification

Summary of Comments: One commenter requested that a section be added to the final rule allowing for users or other third-parties to question AMS certifications.

Agency Response: As already stated, AMS encourages interested parties to contact AMS if they have any questions regarding the appropriateness of an AMS certification of compliance. AMS can use this feedback as a basis for initiating a review to ensure that equipment marketed as certified through this program comply with the standards. The Agency believes this addresses the concern of the commenter sufficiently without the need for the insertion of a new section in the regulations. Accordingly, the regulations will remain unchanged.

Concurrent Reviews for Dairy and Meat and Poultry Equipment

Summary of Comments: One commenter requested that to improve efficiency, dairy and meat and poultry equipment reviews be done concurrently.

Agency Response: Although these regulations do not specifically provide for a "concurrent" review of equipment to be accepted for use under both this and the dairy equipment acceptance program, reviews will be conducted concurrently to all applicable standards upon the request of an applicant using the joint form used for both programs, DA-162, Equipment Review Request.

AMS Accepted Equipment Symbol Confusing

Summary of Comments: One commenter objected to the AMS symbol as confusing and leading observers to believe that the equipment bearing the symbol has the endorsement of FSIS.

Agency Response: AMS disagrees. These regulations are intended to meet the needs expressed by the domestic livestock and poultry industries for a third party evaluation of the sanitary design of processing equipment according to specified standards. These regulations and the services they provide for do not obligate or require any action on the part of FSIS. AMS believes these regulations can be used by the livestock and poultry industries to demonstrate they have had a third party evaluation of the hygienic design and fabrication of processing equipment according to specified standards. The symbol clearly references only AMS as the agency within USDA certifying acceptance. There is no reference, intended or implied, in these regulations of FSIS sanction of the symbol or the acceptance it represents. FSIS regulations specifically identify their responsibility for ensuring all Federally inspected meat and poultry establishments produce safe and wholesome products, regardless of whether the equipment and utensils used to process the products were certified by AMS under the provisions of this regulation.

Size and Format of AMS Accepted Equipment Symbol

Summary of Comments: Four commenters expressed concern over the size and format of the USDA "Accepted Equipment" symbol.

Agency Response: AMS agrees that the regulations were not sufficiently clear on the intended size of the symbol. Section 54.1018 has been revised to include subsection (c) recommending at least a 3/4 by 3/4 inch size for the official AMS symbol, but also allowing for smaller sizes to be used provided they are sufficiently large to be identifiable and legible. Accordingly, symbols of varying size could be used to be compatible with the use and location of the symbol on either the

equipment or promotional materials. The use of the official AMS symbol for this program is consistent with the use of other official identification marks used within other AMS programs.

Comments Referring to Rulemaking Issues

Extension of Comment Period Accompanying the Proposed Rule

Summary of Comments: One commenter requested the comment period be extended.

Agency Response: AMS disagrees. The 60 day comment period which accompanied the ANPRM and the 60 day comment period which accompanied the proposed rule were sufficient to obtain the public comment required to develop the program.

Implement Program on a Trial Basis

Summary of Comments: One commenter requested the program be implemented as a 3-year pilot program.

Agency Response: AMS disagrees. Because this is a voluntary, user-fee-funded service there is no benefit to the program being implemented on a trial basis.

III. Impact Analysis

Executive Order 12866 and the Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), AMS has considered the economic impact of this proposed rule on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such action so that small businesses would not be disproportionately burdened. Accordingly, we have prepared this regulatory flexibility analysis.

Development of this program is required by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106-387, sec. 729). The program will be conducted under the provisions of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*).

AMS is establishing these regulations to conduct a voluntary, user-fee-funded inspection and certification program for equipment and utensils that are used to process livestock and poultry products. Under this proposed program,

manufacturers of new, modified, or reconditioned equipment and utensils designed to process livestock and poultry products who want to have the equipment and utensils they manufacture officially inspected and accepted by AMS as meeting the NSF/3-A standards which outline minimum requirements for cleanability, suitability of materials used in construction, inspectability and durability would apply to AMS.

Under this equipment and utensil acceptance program, equipment and utensil manufacturers seeking AMS acceptance and certification may apply to AMS for an evaluation of their equipment and utensils. Although AMS does not require the drawings, blueprints and a material list for all pieces of equipment or utensils upon application, such blueprints and lists must be submitted as will facilitate the inspection and certification process. Additionally, some equipment and utensils will require AMS to conduct an on-site review at the point of fabrication or where installed and operating in an establishment to fully evaluate the design and construction and execute final acceptance.

To maintain acceptance and certification, these regulations require any manufacturer whose equipment or utensil has been accepted to resubmit the design and fabrication details of the accepted equipment or utensils whenever a change of design or fabrication which may impair the cleanability or hygienic design of the equipment or utensil occurs. Barring changes in equipment or utensil design and fabrication, acceptance is granted for a four year period. When equipment or utensil acceptance nears expiration at the end of the four year period, manufacturers may send a letter stating that no design changes have been made to receive an additional four year acceptance renewal.

This action will benefit manufacturers of equipment and utensils used for processing meat and poultry products and the purchasers of such equipment and utensils by providing AMS certification that the equipment and utensils meet the minimum requirements of voluntary consensus standards for sanitary design. Acceptance by AMS will provide manufacturers and buyers assurance that equipment and utensils can be cleaned, are constructed of suitable materials, are durable, and can be inspected.

This equipment and utensil inspection and certification program affects manufacturers or other vendors of equipment and utensils. The

equipment and utensil manufacturers range in size from small to large concerns. According to the Standard Industrial Classification (SIC) (13 CFR 121.201) which are used by the Small Business Administration to identify small businesses, a small business equipment and utensil manufacturer is defined as a firm with less than 500 employees (SIC Division D, Major Group 20). According to the most complete data available to AMS, it is estimated that there are about 2000 equipment and utensil manufacturers, about 90 percent of these can be classified as small entities.

Previously, FSIS maintained a mandatory prior approval program for equipment and utensil inspection as a prerequisite for use in Federally inspected meat and poultry packing and processing establishments that affected these same entities. Under FSIS' former mandatory prior approval program for equipment, an estimated 2,500 applications for equipment approval were received each year. Evaluation and certification of equipment and utensils is based on the complexity and sophistication of the design and fabrication of the equipment or utensil being evaluated.

The paperwork burden that may be imposed on equipment and utensil manufacturers by this proposed action is further discussed in the section entitled Paperwork Reduction Act that follows.

In addition, we have not identified any relevant Federal rules that are currently in effect that duplicate, overlap, or conflict with this rule. Further, as discussed below, this program will be operated by the AMS Dairy Programs using its relevant fee structure.

Provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, require AMS to develop a voluntary, user-fee-funded program to inspect and certify equipment and utensils used to process livestock and poultry products. Prior to this amendment, similar language appeared in the appropriations acts for fiscal year 1999 (Pub. L. 105-277, sec. 747) and fiscal year 2000 (Pub. L. 106-78, sec. 734). The program will be conducted under the provisions of the Agricultural Marketing Act (AMA) of 1946. Under the AMA of 1946, AMS is required to collect reasonable fees for providing official services provided under this proposed equipment and utensil certification program, to cover as nearly as practicable AMS costs for performing the service, including related administrative and supervisory

costs. Since the procedures used to inspect and certify equipment and utensils used to process livestock and poultry products are similar to those used to inspect and certify dairy processing equipment, AMS has decided to charge the same hourly fees for inspecting and certifying equipment used to process livestock and poultry products. Inspection and certification services are based on the hourly rate for applicants who request services on an hourly basis and appear at 7 CFR Part 58 as published in the **Federal Register** at 62 FR 66258 on December 18, 1997. The current base hourly rate for such service is \$56 per hour for service performed between 6 a.m. and 6 p.m. and \$61.60 for service performed between 6 p.m. and 6 a.m., for the time required to perform the service calculated to the nearest 15-minute period, including the time required for preparation of certificates and reports and the travel time of the equipment review specialist in connection with the performance of the service. A minimum charge of one-half hour will be made for the service pursuant to each request or certificate issued. If an applicant requests that certification service be performed on a holiday, Saturday, or Sunday or in excess of each 8-hour shift Monday through Friday, the applicant would be charged such service at a rate of 1½ times the rate which would be applicable for such service if performed during normal working hours.

AMS estimates that the time required to review and accept an initial submission for simple designs would be 1 hour. For complex designs, AMS estimates that the time required to review and accept an initial submission would be 8 hours. Based on the proposed AMS base hourly fee for service of \$56 per hour, an initial submission of assembly type drawings and corresponding parts and material lists should range from \$56 to \$448. However, the final cost for equipment or utensil inspection and certification would be contingent on a final on-site review of the equipment or utensil at the point of fabrication or under conditions of actual use. The cost of this on-site review would include associated travel and per diem costs in addition to the hourly fee for service. AMS estimates the average time to perform a on-site review for a piece of equipment or utensil to be 12 hours.

The cost for evaluation of equipment or utensils would depend on the complexity of design, location of the equipment or utensil to be evaluated on-site, and whether the manufacturer has provided resource materials that would facilitate inspection of the equipment or

utensil by AMS to determine acceptance. AMS estimates the average total costs to process and in-plant review a piece of equipment or utensil to be \$1,120 plus added travel costs for the required on-site review. Assuming all equipment and utensil manufacturers would use an AMS equipment and utensil certification program to the extent they used the FSIS program, it is estimated that the total cost to the industry under an AMS program would be about \$2,800,000 plus travel costs for on-site reviews annually. Since approximately 90 percent of equipment and utensil manufacturers are small businesses, the estimated share of the total annual industry burden directly affecting small businesses would be \$2,520,000.

As stated in the previous section pertaining to the comments received in response to the proposed rule and the Agency's responses to them, the Act provides that USDA develop a voluntary, user-fee-funded program to inspect and certify equipment used to process livestock and poultry products. Accordingly, the Agency examined alternatives in developing such a program, including an alternative that would have allowed AMS to accredit third-party certifiers to act as agents of AMS, as well as the alternative to allow equipment and utensil manufacturers to self certify their equipment to AMS standards.

AMS considered these alternatives as it evaluated comments received in response to the ANPRM and the proposed rule as the alternatives were considered. The alternative options were rejected by AMS. The statutory language provides that the Secretary inspect and certify agricultural processing equipment. Further, a significant number of comments during the comment periods for the ANPRM and proposed rule which supported an AMS provided service staffed by Federal employees to conduct the evaluations.

In assessing alternatives to the scheme provided for in these regulations, we believe that the provisions contained herein will best accomplish the purpose of the program and at the same time minimize any burden that might be placed upon affected parties.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform and is not intended to have a retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. Further, section 729 of the

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106-387) states that the provision does not affect the authority of the Secretary to carry out the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule.

Paperwork Reduction Act Requirements

The proposed rule (65 FR 35857) contained paperwork submission requirements that were subject to public comment and to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. Chapter 35). In accordance with 5 CFR Part 1320, we included the description of the reporting requirements and an estimate of the annual burden on manufacturers of equipment and utensils used to process livestock and poultry products. As identified in § 54.1004 of these final regulations, the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service would be administered by AMS. During the administration of the service, AMS will expand the use of existing forms currently used by AMS and approved by OMB under 7 CFR part 58, subpart A, Regulations Governing the Inspection and Grading of Manufactured or Processed Dairy Products. The Agency published a **Federal Register** Notice 65 FR 2370, dated January 14, 2000, that expanded the use of these forms and allowed for a 60-day comment period. Additionally, the proposed rule for this action published in the **Federal Register**, 65 FR 35857, dated June 6, 2000, solicited comments from all interested parties concerning the information collection requirements contained in this proposed rule. Comments were specifically invited on the following: (1) The accuracy of the agency's burden estimate of the proposed collection of information including the validity of the methodology and assumptions used; (2) ways to minimize the burden of the collection of information on those who would respond, including through the use of appropriate electronic collection methods; (3) whether the proposed collection of information is sufficient or necessary for the proper performance of the functions of the agency to perform this program; and (4) ways to enhance

the quality, utility, and clarity of the information to be collected.

Of the one hundred comments received for the proposed rule only one comment referenced the Paperwork Reduction Act requirements. This one commenter stated AMS substantially underestimated the number of applications per respondent. The commenter based the comment on the history of their company's applications under the former FSIS prior approval program. The AMS published estimates are based on the expected average number of respondents. Any one applicant may exceed the number of applications submitted based on their voluntary participation in the service provided. However, AMS believes that the published average number of applications is accurate for the program and has not revised its estimates.

OMB Number: 0581-0126.

Expiration Date of Approval: August 31, 2003.

Abstract: The dairy grading program is a voluntary, user-fee-funded program. In order for a voluntary inspection program to perform satisfactorily with a minimum of confusion, there must be written requirements and rules for both Government and industry. The information collections are essential to carry out and administer the inspection and grading program. The information requested is used to identify the product offered for grading, to identify a request from an equipment manufacturer of equipment used in the dairy, meat or poultry industries for evaluation for sanitary design and construction, to identify and contact the party responsible for payment of the inspection, grading or equipment evaluation fee and expense, to identify applicants who wish to be authorized for the display of official identification on product packaging materials, equipment, utensils, or on descriptive or promotional materials.

The equipment and utensil inspection and certification proposed herein would use the forms described above in a program that would be conducted by AMS on a voluntary, fee-for-service basis. Manufacturers of new, modified, or reconditioned equipment and utensils designed to process livestock and poultry products who want to have the equipment or utensils they manufacture officially inspected and accepted by AMS as meeting the NSF/3-A standards which outline minimum requirements for cleanability, suitability of materials used in construction, inspectability and durability would apply to AMS.

For the purposes of the burden estimate, AMS estimated that the hourly

wage for those submitting information would be \$20 per hour. To have equipment and utensils accepted under this program, equipment and utensil manufacturers would submit an application to AMS requesting evaluation of equipment or utensils (Form DA-162). AMS estimates that of the 2000 livestock and poultry equipment and utensil manufacturers, AMS will receive approximately 2500 applications per year or, on average, 1.25 applications from each manufacturer. Form DA-162 requires 0.038 hours to complete. The total annual burden on the industry for this proposed collection of information would be 95 hours or \$1,900 annually. Since AMS does not require the drawings, blueprints and a material list to be submitted, they have not been included in this burden estimate.

Manufacturers whose equipment or utensil receives AMS acceptance may, upon request, be issued an official certificate as proof that the equipment or utensil meets NSF/3-A standards and is therefore accepted. Since completion of this certificate is performed by AMS, it has also not been included in this burden estimate. Upon written application (Form DA-155 and Form DA-156), manufacturers of accepted equipment or utensils may receive permission to display the official mark of acceptance on equipment and utensils, or in promotional literature as illustrated in the regulatory text (Figure 1). Form DA-155 is a one-time application from each manufacturer and, therefore, has been estimated to only be sent by a respondent once in every four-year cycle of equipment and utensil approval. The estimate of the total annual burden of this collection of information is 10.5 hours or \$210 annually. Form DA-156 is submitted by a manufacturer each time there is a request to use the symbol on a piece of equipment or utensil, or in promotional literature. AMS estimates that it would receive one request each year to use the symbol on equipment or utensils, or in promotional material for each piece of equipment or utensil accepted. Therefore, AMS estimates that the total annual burden for this collection of information would be 42.5 hours or \$850 annually.

Manufacturers whose equipment or utensil does not meet the design and fabrication requirements of the NSF/3-A standards and does not receive acceptance by AMS may appeal AMS' determination. The manufacturers would make a request for appeal service with the Chief, Dairy Grading Branch by completing and submitting a request for service (Form DA-162) to have

equipment or utensils reevaluated. The appeal process is set forth in sections § 54.1020 through § 54.1027 of the proposed regulations. As the AMS Dairy Program has never received an appeal for service under its current equipment acceptance program, AMS has estimated that 1% of applicants will appeal service in this estimate of the burden of the collection of information. Accordingly, with 2500 applications per year and Form DA-162 requiring 0.038 hours to complete and an estimate of only 1 percent of applicants requiring an appeal, the total annual burden on the industry for this proposed collection of information would be 0.95 hours or \$19 annually.

Any manufacturer whose equipment or utensil has been certified shall resubmit the design and fabrication details of the certified equipment or utensil whenever a change of design or fabrication has occurred. Certification of equipment or utensils that have not changed remains in effect for a period of four years. If no changes in equipment or utensil design or fabrication have occurred over the four year period since the last certification was made, manufacturers must submit a certificate of conformance signed by the chief engineering officer and chief executive officer of the company stating that no design changes have been made to receive certification renewal. AMS estimates that it would receive one such request every four years for each piece of equipment or utensil accepted. AMS estimates that the total annual burden for this collection of information would be 52 hours or \$1,040 annually.

Collectively, AMS estimated that the total annual burden for the collection of information would be 200.95 hours or \$4019 annually.

1. Equipment Review Request—Form DA-162

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.038 hours per response.

Respondents: Manufacturers of equipment and utensils used to process livestock and poultry products.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 1.25.

Estimated Total Annual Burden on Respondents: 95 hours.

Total Cost: \$1,900.

2. Application To Use official ID—Form DA-155

Estimate of Burden: Public reporting burden for this collection of information

is estimated to average 0.021 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.250.

Estimated Total Annual Burden on Respondents: 10.5 hours.

Total Cost: \$210.

3. Request To Display Official ID—Form DA-156

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.017 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 1.25.

Estimated Total Annual Burden on Respondents: 42.5 hours.

Total Cost: \$850.

4. Appeal—Equipment Review Request—Form DA-162

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.038 hours per response.

Respondents: Manufacturers of equipment and utensils used to process livestock and poultry products.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.0125.

Estimated Total Annual Burden on Respondents: 0.95 hours.

Total Cost: \$19.

5. Letter Requesting Renewal of Acceptance

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.083 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.313.

Estimated Total Annual Burden on Respondents: 52 hours.

Total Cost: \$1,040.

Estimated Total Annual Burden on Respondents: 200.95 hours total or 0.1 hours per respondent.

Estimated Total Annual Costs: \$4,019 or \$2 per respondent.

It is found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because this (1) is a voluntary, user-fee-funded program; (2) equipment manufacturers are aware of the provisions of this rule, which a 60-day comment period was provided for in the proposed rule; and (3) have already begun to request this service.

List of Subjects in 7 CFR Part 54

Food Grades and standards, Food labeling, Meat and meat products.

For the reasons set forth in the preamble 7 CFR Part 54 is amended as follows:

PART 54—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION, AND STANDARDS)

1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627; Pub. L. 106–387, sec. 729.

2. In Part 54 a new Subpart C consisting of §§ 54.1001 through 54.1034 is added to read as follows.

Subpart C—Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products

Sec.

- 54.1001 Meaning of words.
- 54.1002 Terms defined.
- 54.1003 Designation of official certificates, memoranda, marks, and other identifications for purposes of the Agricultural Marketing Act of 1946.
- 54.1004 Administration and implementation.
- 54.1005 Basis of service.
- 54.1006 Kind of service.
- 54.1007 Availability of service.
- 54.1008 How to obtain service.
- 54.1009 Order of furnishing service.
- 54.1010 When request for service deemed made.
- 54.1011 Withdrawal of application or request for service.
- 54.1012 Authority of agent.
- 54.1013 When an application may be rejected.
- 54.1014 Accessibility of equipment and utensils; access to establishments.
- 54.1015 Official reports, forms, and certificates.
- 54.1016 Advance information concerning service rendered.
- 54.1017 Authority to use official identification.
- 54.1018 Form of official identification and approval for use.
- 54.1019 Renewal of Acceptance Certification.
- 54.1020 Appeal service; marking equipment or utensils on appeal; requirements for appeal; certain determinations not appealable.
- 54.1021 Request for appeal service.
- 54.1022 When request for appeal service may be withdrawn.
- 54.1023 Denial or withdrawal of appeal service.
- 54.1024 Who shall perform appeal service.
- 54.1025 Appeal reports.
- 54.1026 Superseded reports.
- 54.1027 Application of other regulations to appeal service.

- 54.1028 Fees and other charges for service.
 54.1029 Payment of fees and other charges.
 54.1030 Identification.
 54.1031 Errors in service.
 54.1032 Denial or withdrawal of service.
 54.1033 Confidential treatment.
 54.1034 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

Subpart C—Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products

§ 54.1001 Meaning of words.

For the purposes of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 54.1002 Terms defined.

Act. The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*).

Administrator. The Administrator of the Agricultural Marketing Service (AMS), United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Applicant. Any person who applies for service under the regulations in this subpart.

Branch. The Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service.

Chief. The Chief of the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, or the representative to whom authority has been delegated to act in the stead of the Chief.

Compliance. Conformity of a processing system, piece of processing equipment, or a utensil to identified standards.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Dairy Programs of the Agricultural Marketing Service or any officer or employee of the Dairy Programs to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated to act in the stead of the Deputy Administrator.

Design Review Specialist. An employee of the Branch who determines and certifies or otherwise evaluates the compliance of equipment or utensils under the regulations.

Design Evaluation and Certification Service. The service established and conducted under the regulations for the

evaluation and certification or other identification of the compliance of equipment or utensils used for the slaughter, processing or packaging of livestock and poultry products (Referred to hereinafter as “equipment” or “utensils”) with sanitary specifications or standards.

Fabricator. Commercial entity engaged in the manufacture or assembly of equipment or utensils.

Financially interested person. Any person having a financial interest in the equipment or utensils involved, including but not limited to the designer, fabricator, or user of the equipment or utensils.

Legal Holiday. Those days designated as legal public holidays in Title 5, United States Code, section 6103(a).

Person. Any individual, partnership, corporation, or other legal entity, or Government agency.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing in a container.

Program. The Dairy Programs of the Agricultural Marketing Service.

Standards. The most recent version of standards for equipment and utensils formulated by the NSF/3–A Joint Committee on Food Processing Equipment (Referred to hereinafter as “NSF/3–A”).

The regulations. The regulations in this Subpart.

§ 54.1003 Designation of official certificates, memoranda, marks, and other identifications, for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended provides criminal penalties for various specified offenses relating to official certificates, memoranda, and marks or other identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this subpart, the terms listed in paragraphs (a) through (c) of this section shall have the respective meanings specified:

(a) “Official certificate” means any form of certification, either written or printed, used under the regulations to certify with respect to the evaluation, review, condition, or acceptance of equipment or utensils (including the compliance of equipment or utensils with applicable standards).

(b) “Official memorandum” means any initial record of findings made by an authorized employee of the Dairy Grading Branch in the process of determining compliance, evaluating, or reviewing equipment or utensils pursuant to the regulations, any processing or in plant-operation report made by an authorized Dairy Grading Branch employee in connection with determining compliance, evaluating, or reviewing equipment or utensils under the regulations, and any report made by an authorized employee of the Dairy Grading Branch of any other services performed pursuant to the regulations.

(c) “Official mark” or “other official identification” means any form of mark or other identification, including those prescribed in § 54.1018; used under the regulations in marking any equipment or utensils or displayed as an indication that the equipment or utensils has been evaluated by AMS (including the compliance of the equipment or utensils with applicable standards).

§ 54.1004 Administration and implementation.

The Administrator designates the administration and implementation of the Certification of Sanitary Design and Fabrication of Equipment Used in the Processing of Livestock and Poultry Products service to the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service. The Chief is charged with the administration, under the general supervision and direction of the Deputy Administrator, of the regulations and the Act insofar as they relate to equipment or utensils used to process livestock and poultry products.

§ 54.1005 Basis of service.

(a) Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service shall be performed in accordance with the provisions of this subpart, the instructions and guidelines issued or approved by the Chief and the applicable standards developed by the NSF/3–A.

(b) Copies of standards developed by NSF/3–A that AMS will inspect and certify to are available, for a nominal fee, from NSF International at www.nsf.org or contact Techstreet, 310 Miller Avenue, Ann Arbor, MI 48103; Phone (800) 699–9277. Copies of all other instructions and guidelines can be obtained from, and copies of standards developed by NSF/3–A may be inspected at, the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Programs, Dairy Grading Branch; Room 2746–S; 1400

Independence Ave., SW., Washington, DC 20250-6456.

(c) All services provided in accordance with the regulations shall be rendered without discrimination on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 54.1006 Kind of service.

Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service under the regulations shall consist of the evaluation, certification and/or identification, upon request by the applicant, of the adherence of the design and fabrication of equipment and utensils to sanitary principles and criteria under applicable standards identified in this subpart. Equipment or utensils having an identical design, materials of construction, and fabrication, except for scaling up or down in size, may be submitted for evaluation as a model line or series. Determination as to equipment or utensils compliance with standards for materials of fabrication or method of fabrication may be based upon information received from the fabricator.

§ 54.1007 Availability of service.

Service under these regulations may be made available to the designers, fabricators, users, or other interested person or party, of the equipment or utensils. Subject to the provisions of this subpart, services shall be performed only when a qualified design review specialist is available, and when the location of the equipment or utensils, evaluation facilities and conditions, as determined by the Chief, are suitable for conducting such service.

§ 54.1008 How to obtain service.

(a) *Application.* Any person may apply to the Chief for service under the regulations with respect to equipment or utensils in which the applicant is financially interested. The application shall be made on a form approved by the Chief. In any case in which the service is intended to be furnished at an establishment not operated by the applicant, the applicant shall be responsible for obtaining approval for accessibility of the equipment or utensil from the operator of such establishment and such approval shall constitute an authorization for any employees of the Department to enter the establishment for the purpose of performing their functions under the regulations. The application shall state:

(1) The name and address of the establishment at which service is desired;

(2) The name and post office address of the applicant;

(3) Identification of the party that will be responsible for payment of all services rendered in response to the request;

(4) The type of equipment or utensil presented for evaluation;

(5) The date(s) on which service is requested to be performed; and

(6) The signature of the applicant (or the signature and title of the applicant's representative) and date of the request.

(b) *Notice of eligibility for service.* The applicant for service will be notified whether the applicant's application is approved.

§ 54.1009 Order of furnishing service.

Service under the regulations shall be furnished to applicants, insofar as practicable and subject to the availability of a qualified design review specialist, in the order in which requests therefor are received, insofar as consistent with good management, efficiency and economy. Precedence will be given, when necessary, to requests made by any government agency and to requests for appeal service under § 54.1021.

§ 54.1010 When request for service deemed made.

A request for service under the regulations shall be deemed to be made when received by the Branch. Records showing the date and time of the request shall be maintained.

§ 54.1011 Withdrawal of application or request for service.

An application or a request for service under the regulations may be withdrawn by the applicant at any time before the application is approved or prior to performance of service. The applicant shall be responsible for payment, in accordance with § 54.1028 and § 54.1029, of any expenses already incurred by the Agricultural Marketing Service in connection therewith.

§ 54.1012 Authority of agent.

Proof of the authority of any person making an application or a request for service under the regulations on behalf of any other person may be required at the discretion of the Deputy Administrator or Chief or other employee receiving the application or request under § 54.1008.

§ 54.1013 When an application may be rejected.

(a) An application or a request for service may be denied by the design

review specialist, with the concurrence of the Deputy Administrator or Chief when:

(1) For administrative reasons such as the non-availability of personnel to perform the service;

(2) The application or request relates to equipment or utensils which are not eligible for service under § 54.1006;

(3) The applicant fails to meet either the application requirements prescribed in this subpart or the conditions for receiving such service;

(4) The equipment or utensil is owned by, or located on the premises of, a person currently denied the benefits of the Act;

(5) The applicant has substantial financial ties to a person who is currently denied the benefits of the Act, or who has been adjudged, in an administrative or judicial proceeding, responsible in any way for a current denial of benefits of the Act to any other person.

(6) The applicant is currently denied services under the Act.

(7) Any fees billed to the applicant are not paid within 30 days; or

(8) The applicant has failed to comply with the Act or this subpart or with the instructions or guidelines issued hereunder.

(b) The Chief shall provide notice to an applicant whose application is rejected, and shall explain the reason(s) for the rejection. If such notification is made verbally, written confirmation may be provided.

§ 54.1014 Accessibility of equipment and utensils; access to establishments.

(a) The applicant shall cause equipment and utensils to be made easily accessible for examination and to be so placed, with adequate illumination to facilitate evaluation for compliance. The applicant shall furnish or make available any necessary tools; such as boroscope, profilometer, disassembly tools, ladders, radius gauges, and the like; necessary to complete the evaluation.

(b) Supervisors of USDA design review specialists responsible for maintaining uniformity and accuracy of service under the regulations shall have access to all parts of establishments covered by approved applications for service under the regulations, for the purpose of examining all equipment or utensils in the establishments which have been or are to be evaluated for compliance with standards or which bear any marks of compliance.

§ 54.1015 Official reports, forms, and certificates.

(a) *Report.* The design review specialist shall prepare, sign, and issue

a narrative report covering the observations, comments and recommendations based on the evaluation for conformance with standards of equipment and utensils as provided for in § 54.1005 and indicate the fees and other charges incurred for the services rendered.

(b) *Forms.* Form DA-161 is the official certificate for equipment or utensils evaluated and is accepted under the regulations. Issuance of this certificate is optional at the request of the applicant.

(c) *Distribution.* The original report and official certificate (if requested) shall be delivered or mailed to the applicant or other persons designated by the applicant. Other copies shall be forwarded as required by agency, program, and branch instructions. Additional copies will be furnished to any person financially interested in the equipment or utensil involved with the concurrence of the applicant and upon payment of fees, as provided in § 54.1028 and § 54.1029.

§ 54.1016 Advance information concerning service rendered.

Upon request of any applicant, all or any part of the contents of any report

issued to the applicant under the regulations, or other notification concerning the determination of compliance of equipment or utensils for such applicant may be transmitted by facsimile transmission to the applicant, or to any person designated by the applicant at the applicant's expense.

§ 54.1017 Authority to use official identification.

The Chief may authorize an applicant or any persons designated by the applicant to use the official identification symbol to mark equipment or utensils, or for display in descriptive or promotional materials providing the equipment or utensils is evaluated pursuant to this subpart and found to be in compliance.

§ 54.1018 Form of official identification and approval for use.

(a) The official identification symbol approved for use on equipment, utensils, or descriptive or promotional materials shall appear in the form and design shown in Figure 1.

(b) The official identification symbol on equipment or utensils shall be displayed by etching or the placement

of a non-removable sticker located in close proximity to the equipment identification plate.

(c) The official identification symbol is recommended to be at least 3/4 inch by 3/4 inch in size. Symbols which are smaller in size will be considered provided they are sufficiently large to be identifiable and legible.

(d) The official identification symbol shall not be used in descriptive and promotional materials without prior approval by the Chief. The official identification symbol, if used, on the descriptive or promotional materials shall be printed as part of the text or format.

(e) An applicant shall submit to the Chief of the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, Washington, D.C. 20090-6456, an application, if one is not on file, requesting approval to use the official identification symbol on officially accepted equipment and in descriptive or promotional materials.

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Figure 1. Official identification symbol.



§ 54.1019 Renewal of acceptance certification.

The manufacturer of any equipment or utensil which has been issued a report or certification stating acceptance of compliance shall resubmit the design and fabrication details of any change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil. If no change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil has occurred during the period of four years after the date of the most recent report stating acceptance of compliance or if no design or fabrication changes have been made, the applicant may submit a certificate of conformance signed by the chief engineering officer and the chief executive officer of the company stating that no design changes have been made to the specified equipment or utensil.

§ 54.1020 Appeal service; marking equipment or utensils on appeal; requirements for appeal; certain determinations not appealable.

(a) Appeal service is a re-evaluation of the compliance of a piece of equipment, portion of a piece of equipment, or utensil to design or fabrication criteria according to the standards prescribed by this subpart.

(b) Only the original applicant or their representative may request appeal service requesting a reevaluation of the original determination of the design and fabrication of the equipment or utensil for compliance with the standards specified in this subpart.

(c) Appeal service will not be furnished for:

(1) A piece of equipment, portion of a piece of equipment, or utensil which has been altered or has undergone a material change since the original service.

(2) For the purpose of obtaining an up-to-date report or certificate which does not involve a question as to the correctness of the original service for the piece of equipment, portion of a piece of equipment, or utensil.

§ 54.1021 Request for appeal service.

(a) Except as otherwise provided in § 54.1020, an applicant or their representative may request appeal service when the applicant or their representative disagree with the determination as to compliance with the standard of the piece of equipment, portion of a piece of equipment, or utensil as documented in the applicable report.

(b) A request for appeal service shall be filed with the Chief, directly or

through the design review specialist who performed the original service. The request shall state the reasons for the disagreement with the original determination and may be accompanied by a copy of any previous certificate or report, or any other information which the applicant may have received regarding the piece of equipment, portion of a piece of equipment, or utensil at the time of the original service. Such request may be made orally (including by telephone) or in writing (including by facsimile transmission). If made orally, the Dairy Grading Branch employee receiving the request may require that it be confirmed in writing.

§ 54.1022 When request for appeal service may be withdrawn.

A request for appeal service may be withdrawn by the applicant at any time before the appeal service has been performed, upon payment of any expenses already incurred under the regulations by the Branch in connection therewith.

§ 54.1023 Denial or withdrawal of appeal service.

A request for appeal service may be rejected or such service may be otherwise denied to or withdrawn from any person in accordance with the procedure set forth in § 54.1013(a), if it appears that the person or product involved is not eligible for appeal service under § 54.1020, or that the identity of the piece of equipment, portion of a piece of equipment, or utensil has been lost; or for any of the causes set forth in § 54.1032.

§ 54.1024 Who shall perform appeal service.

Appeal service for equipment or utensils shall be performed by the Chief or a design review specialist designated by the Chief. No design review specialist may perform appeal service for any piece of equipment, portion of a piece of equipment or utensil for which the original design review specialist performed the initial evaluation service.

§ 54.1025 Appeal reports.

After appeal service has been performed for any piece of equipment, portion of a piece of equipment or utensils, an official report shall be prepared, signed, and issued referring specifically to the original report and stating the determination of the re-evaluation of compliance of the piece of equipment, portion of a piece of equipment or utensil.

§ 54.1026 Superseded reports.

The appeal report shall supersede the original report which, thereupon, shall become null and void for all or a portion of the report pertaining to the appeal service and shall not thereafter be deemed to show the compliance of the equipment or utensils described therein. However, the fees charged for the original service shall not be remitted to the applicant who filed the appeal.

§ 54.1027 Application of other regulations to appeal service.

The regulations in this subpart shall apply to appeal service except insofar as they are inapplicable.

§ 54.1028 Fees and other charges for service.

Fees and other charges equal as nearly as may be to the cost of the services rendered shall be assessed and collected from applicants in accordance with the provisions for Fees and Charges set forth in 7 CFR part 58, Subpart A, Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products, sections §§ 58.38, 58.39, 58.41, 58.42, and 58.43, as appropriate.

§ 54.1029 Payment of fees and other charges.

Fees and other charges for service shall be paid upon receipt of billing for fees and other charges for service. The applicant shall remit by check, draft, or money order, made payable to the Agricultural Marketing Service, USDA, payment for the service in accordance with directions on the billing, and such fees and charges shall be paid in advance if required by the official design review specialist or other authorized official.

§ 54.1030 Identification.

All official design review specialists and supervisors shall have their Agricultural Marketing Service identification cards in their possession at all times while they are performing any function under the regulations and shall identify themselves by such cards upon request.

§ 54.1031 Errors in service.

When a design review specialist, supervisor, or other responsible employee of the Branch has evidence of inaccurate evaluation, or of incorrect certification or other incorrect determination or identification as to the compliance of a piece of equipment or utensil, such person shall report the matter to the Chief. The Chief will investigate the matter and, if deemed advisable, will report any material errors to the owner or the owner's agent. The Chief shall take appropriate action

to correct errors found in the determination of compliance of equipment or utensils, and the Chief shall take adequate measures to prevent the recurrence of such errors.

§ 54.1032 Denial or withdrawal of service.

(a)(1) *Bases for denial or withdrawal.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person who, or whose employee or agent in the scope of the person's employment or agency:

(i) Has wilfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under the regulations;

(ii) has given or attempted to give, as a loan or for any other purpose, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function under the regulations;

(iii) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in the performance of duties under the regulations by intimidation, threats, assaults, abuse, or any other improper means;

(iv) has knowingly falsely made, issued, altered, forged, or counterfeited any official certificate, memorandum, mark, or other identification;

(v) has knowingly uttered, published, or used as true any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark or identification;

(vi) has knowingly obtained or retained possession of any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark or identification, or of any equipment or utensil bearing any such falsely made, issued, altered, forged, or counterfeited mark or identification;

(vii) has applied the designation "USDA Accepted Equipment", "AMS Accepted Equipment", "USDA Approved Equipment", "AMS Approved Equipment", "Approved By USDA", "Approved By AMS", "Accepted By USDA", "Accepted By AMS", "USDA Approved", "USDA Accepted", "AMS Approved", "AMS Accepted", or any other variation of wording which states or implies official sanction by the United States Department of Agriculture by stamp, or brand directly on any equipment or

utensil, or used as part of any promotional materials which has not been inspected and deemed in compliance with this subpart; or,

(viii) has in any manner not specified in this paragraph violated subsection 203(h) of the AMA: *Provided*, That paragraph (a)(1)(vi) of this section shall not be deemed to be violated if the person in possession of any item mentioned therein notifies the Deputy Administrator or Chief without such delay that such person has possession of such item and, in the case of an official identification, surrenders it to the Chief, and, in the case of any other item, surrenders it to the Deputy Administrator or Chief or destroys it or brings it into compliance with the regulations by obliterating or removing the violative features under supervision of the Deputy Administrator or Chief: *And provided further*, That paragraphs (a)(1) (ii) through (vii) of this section shall not be deemed to be violated by any act committed by any person prior to the making of an application of service under the regulations by the principal person. An application or a request for service may be rejected or the benefits of the service may be otherwise denied to, or withdrawn from, any person who operates an establishment for which such person has made application for service if, with the knowledge of such operator, any other person conducting any operations in such establishment has committed any of the offenses specified in paragraphs (a)(1) (i) through (vii) of this section after such application was made. Moreover, an application or a request for service made in the name of a person otherwise eligible for service under the regulations may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, such a person:

(A) In case the service is or would be performed at an establishment operated:

(1) By a corporation, partnership, or other person from whom the benefits of the service are currently being withheld under this paragraph; or

(2) By a corporation, partnership, or other person having an officer, director, partner, or substantial investor from whom the benefits of the service are currently being withheld and who has any authority with respect to the establishment where service is or would be performed; or

(B) In case the service is or would be performed with respect to any product in which any corporation, partnership, or other person within paragraph (a)(1)(viii)(A)(1) of this section has a contract or other financial interest.

(2) *Procedure.* All cases arising under this paragraph shall be conducted in accordance with the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth in 7 CFR §§ 1.130 through 1.151 and the Supplemental Rules of Practice in part 50, 7 CFR § 50.1 *et seq.*

(b) *Filing of records.* The final orders in formal proceedings under paragraph (a) of this section to deny or withdraw the service under the regulations (except orders required for good cause to be held confidential and not cited as precedents) and other records in such proceedings (except those required for good cause to be held confidential) shall be filed with the Hearing Clerk and shall be available for inspection by persons having a proper interest therein.

§ 54.1033 Confidential treatment.

Every design review specialist providing service under these regulations shall keep confidential all information secured and not disclose such information to any person except an authorized representative of the Department.

§ 54.1034 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

The following control number has been assigned to the information collection requirements in 7 CFR Part 54, Subpart C, by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

7 CFR section where requirements are described	Current OMB control No.
54.1008(a)	0581-0126
54.1017	0581-0126
54.1018(e)	0581-0126
54.1019	0581-0126
54.1020	0581-0126
54.1021	0581-0126

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Barry L. Carpenter,

Deputy Administrator, Livestock and Seed Program.

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