Compliance Guidelines for Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments

Food Safety and Inspection Service U.S. Department of Agriculture

Note: The Food Safety and Inspection Service (FSIS) is publishing this final compliance guideline after receiving Office of Management and Budget (OMB) approval of information collection under the Paperwork Reduction Act related to Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedures (Sanitation SOP) video records. FSIS has revised these final compliance guidelines to reflect comments received.

A total of 1,217 comments were received. Of those, 813 were a campaign form letter requesting that video be mandated in establishments. Another 400 comments were general statements that video should be made mandatory in establishments, concerns about worker safety, and concerns about inhumane handling. An additional comment was to require an accredited third party to audit mandatory video use in establishments.

Requiring video cameras in establishments is not necessary to ensure that animals are handled humanely in conjunction with slaughter. FSIS inspectors are required to conduct hands-on inspection to verify establishments are meeting regulatory requirements for humane handling in livestock and good commercial practices in poultry.

FSIS incorporated the three other comments into the final guidelines. This includes more clearly explaining these items:

- video records not subject to routine access by FSIS: video records not
 designated by the establishment for use in HACCP plans or Sanitation SOPs,
 video records that are used for food defense security, or video records used for
 other purposes that do not require recordkeeping; such records would be subject
 to FSIS access during an investigation of food safety, food security, or any
 unlawful actions
- use of video technology as a tool to supplement establishments' hands-on humane handling and good commercial practice activities; video technology cannot replace FSIS hands-on inspection activities
- the importance of effective implementation of video monitoring to result in trustworthy and accurate information that helps to prevent inhumane treatment or poor commercial practices; video cameras should be positioned and operate in such a way to allow continuous viewing of all steps from unloading to stunning

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I. Purpose

This compliance guide was written in response to U.S. Department of Agriculture's Office of the Inspector General (OIG) recommendations (December 2008) to provide information to industry on the use of video or other electronic monitoring or recording equipment to help it maintain compliance with federal regulations, including humane treatment of livestock and the use of good commercial practices in poultry. This document includes recommendations rather than regulatory requirements.

FSIS is providing this **guidance** to advise establishments that video or other electronic monitoring or recording equipment can be used in federally inspected establishments. This guide informs establishments of the Agency's expectations if they decide to use this type of equipment to create records to meet requirements of the Hazard Analysis of Critical Control Points (HACCP) regulations or the regulations governing Sanitation Standard Operating Procedures (Sanitation SOPs) or associated prerequisite programs. In addition, this guide provides information on issues establishments should consider if they use this equipment for any other purpose, such as part of their food defense plans.

Most importantly, this guide provides information and encourages industry to use this technology, particularly as part of its systematic approach to ensure that livestock are handled humanely and that poultry good commercial practices are followed.

Although FSIS recognizes that the use of video or other electronic monitoring or recording equipment may assist establishments in meeting federal requirements or for other purposes it cannot be used in a manner to harass, intimidate or interfere with FSIS Inspection Program Personnel (IPP) in the performance of their duties.

II. Background

Video or other electronic monitoring or recording technology is rapidly changing to meet increasing needs of businesses to become more efficient, increase productivity, and maintain security. Before the 1990s, traditional video technology was analog-based and was used for simple surveillance of premises with a closed circuit television camera and a video cassette recorder (VCR). With the VCR this video system could preserve information (or evidence) which allowed review of past events captured on the video.

Further developments improved video capabilities and their applications, but the most revolutionary change, enabled by Internet and local area network (LAN) availability, was full digitization of both camera and recorder. In these digital video surveillance systems, a digitized camera signal travels over a LAN line to a computer or server. The server or computer in turn manages and analyzes all incoming information resulting in an array of capabilities.

A fully digitized system can encrypt data and integrate with other systems or multiple locations. It can retrieve data from remote locations, and use software that enhances or

manipulates images for better viewing and detection of adverse events. It can also direct the video surveillance cameras on-site to detect specific criteria developed to measure process control or compliance. One application of a system of this type in the food industry is video auditing. This application allows the operator to select criteria or risk areas for video monitoring from a remote location to determine whether the selected activities or procedures are indeed taking place. This application is called remote video auditing (RVA).

These types of systems, from early traditional to fully digital, are forms of electronic records if they provide permanent evidence or information about past events as do other electronic recordings, such as data loggers or continuous recording devices. However, "live feed video" from a surveillance camera would not be a record if it is not recorded or maintained.

III. Recordkeeping Requirements for Video or Other Electronic or Recording Equipment

When video or other electronic monitoring or recording equipment provides permanent evidence of or information about past events, an electronic record is created. Electronic records may substitute for paper and handwritten records and are subject to the same statutory and regulatory requirements. As with paper records, video or other electronic monitoring or recording records may be designated as a record to meet HACCP and Sanitation SOP requirements or may be used for other purposes, such as Food Defense plans.

Records not designated for HACCP or Sanitation SOPs are not subject to 9 CFR Parts 416 or 417 recordkeeping regulations; however, any monitoring or verification activities that have an impact on the hazard analysis are subject to 9 CFR Part 417. Additionally, FSIS may request access to all applicable establishment records in the event of an official investigation related to issues such as food defense, food safety, unlawful actions, or provisions of 9 CFR 320. For example, if potential product tampering has been detected, FSIS may request access to an establishment's recordings used in carrying out their Food Defense plan in the course of that investigation.

The FMIA (21 USC 642), PPIA (21 USC 460(b)), and Egg Products Inspection Act (EPIA) (21 USC 1040) contain broad authority requiring certain classes of persons, firms, and corporations in the meat, poultry, and processed egg products business to maintain and provide FSIS with access to records related to their operations. Recordkeeping requirements apply to persons, firms, and corporations that prepare, freeze, pack, label, buy, sell, transport, store, and import meat food products (21 USC

systems.

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¹ Other digital imaging include the following: scanning (bar code scanners); software for scanning items; storage media, such as magnetic or optical disks; programs that can convert images into text-searchable files such as optical character recognition programs; indexing software, for making images more accessible; and storage devices, such as CD jukeboxes or hierarchical storage management (HSM)

642(a) (1), (2)). The statutes require that these businesses maintain production records, bills of sale, invoices, shipping and receiving records, and related business records.

IV. Use of Video or Other Electronic Monitoring or Recording Equipment to Verify Livestock Humane Slaughter Activities or Poultry Good Commercial Practices

FSIS encourages federally inspected establishments to consider using video or other electronic monitoring or recording equipment as part of an overall systematic approach to maintain humane handling or good commercial practices to comply with regulatory and statutory requirements. FSIS encourages establishments to use video technology not as a substitute, but as a supplement to enhance their hands-on activities. The use of video technology should be effectively implemented to result in trustworthy and accurate information that helps to prevent inhumane treatment or inadequate good commercial practices.

Video or other electronic monitoring or recording equipment provides an establishment with continuous information on what is occurring with humane handling, instead of relying on periodic observations or spot checks. Establishments should strategically place cameras to provide continuous multi-dimensional views of an establishment's processes, such as from unloading through stunning. Some systems can bring together information in regards to humane handling, food safety, compliance, and product quality at one time. Thus, video or other electronic monitoring or recording equipment can provide new information for establishments to improve process control, as well as to provide feedback for employee training.

A type of video or other electronic monitoring or recording equipment that has been developed specifically to verify humane handling or good commercial practices is RVA. In a RVA system the video feed or recording from cameras placed to continuously monitor critical live animal handling and stunning areas, is linked through a computer server to allow the records to be viewed on the web at a remote location by an auditor. The auditor views the video daily and generates reports, containing statistical summaries, web hyperlinks to the video and still images captured through the RVA systems. Such systems may also supply immediate notification to the establishment when pre-determined activities or increased incidences of activities occur.

Establishments may determine that the records from using video or other electronic monitoring or recording equipment can help them develop and maintain a systematic approach to humane handling and good commercial practice. The systematic approach means one in which establishments focus on treating livestock or poultry in such a

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² "Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to meet such Requirements," (69 FR 54625, September 9, 2004) and "Treatment of Live Poultry Before Slaughter" (70 FR 56624, September 28, 2005).

manner as to minimize excitement, discomfort, and accidental injury for the entire time that live livestock or poultry are held in connection with slaughter. The systematic approach involves specific steps (four in livestock and three in poultry) to ensure that there is an integrated approach to humanely handling the animals and good commercial practices in poultry. The steps are:

- 1. Identify where and under what circumstances livestock may experience excitement, discomfort, or accidental injury while being handled in connection with the slaughter process. Assess circumstances in which poultry may experience excitement, discomfort, or accidental injury while being handled.
- 2. Design facilities and implement practices that will minimize livestock discomfort and injury in accordance with existing regulations. Take steps to minimize the possibility of excitement, discomfort, and accidental injury of poultry.
- 3. Periodically evaluate the system to see whether there is any excitement, discomfort, or injury as livestock move from being unloaded from trucks to the knock box. Evaluate periodically how poultry are being handled and slaughtered to ensure (a) that any excitement, discomfort, or accidental injury is being minimized; (b) that all poultry are slaughtered in a manner that results in thorough bleeding of the poultry carcass; and (c) that breathing has stopped before scalding.
- 4. Improve or adjust operations in livestock to minimize the excitement, discomfort, or possibility of accidental injury.

A livestock establishment in Step 3, for example, might use video monitoring of the holding pens to determine whether employees are in fact minimizing excitement, discomfort, and accidental injury of animals. Similarly poultry establishments may use video or other electronic monitoring or recording equipment to monitor live areas to determine whether employees are taking actions to minimize excitement, discomfort, and accidental injury, as they position the birds for stunning and slaughter. Thus, the use of video or other electronic monitoring or recording equipment to support an overall systematic approach can provide assurance that the establishment intends to meet the requirements for humane handling and good commercial practices.

Although FSIS encourages establishments to use appropriate video or other electronic monitoring or recording equipment, video surveillance from a remote location would not provide an effective method for FSIS to assess the consciousness of animals, as the Agency is required to do. Assessing consciousness of animals involves direct observation from several visual perspectives and sometimes touching the animal's eyes or other parts.

The use of video technology does not replace FSIS on-site verification activities of humane handling and good commercial practices. IPP need to conduct hands-on verification activities to assess whether an establishment's handling and slaughter

activities comply with 9 CFR Part 313, 21 USC 603(b), and section 1902 of the HMSA (7 USC 1902). Similarly for poultry, IPP need to assess by hands-on verification whether birds are handled and slaughtered in a manner consistent with good commercial practices (9 CFR Part 381.65 (b)), and whether they are dying other than by slaughter (9 CFR Part 381. 90) (PPIA) 21 US 453(g) (5)).

FSIS IPP are trained in humane handling and understand that they are obligated to take immediate action when they directly observe an egregious humane slaughter violation. If IPP were to observe an egregious event on an establishment's live feed video for example, IPP are expected to go directly to the place at the establishment where the event was occurring and ensure that the event has ended and does not persist. They are also expected to document appropriately the observation, even when the event witnessed is no longer occurring and to take any appropriate actions according to instructions in relevant FSIS Notices and Directives.

NOTE: IPP are not to focus on the live feed video since it does not have a recording component and therefore cannot create a record. While the live feed may, on a rare occasion, point to a problem, it is a much more efficient use of IPP's time to perform the assigned tasks than to specifically focus on the live feed video, on the off chance that an egregious situation will be shown.

For similar reasons, FSIS believes that IPP need to conduct hands-on verification activities for ante-mortem inspection (9 CFR Part 309 and Part 381.70 - 75).

V. Use of Video or Other Electronic Monitoring or Recordings for Food Defense Purposes

FSIS has prepared guidance documents for food processors to use to assist federally and State-inspected establishments that produce meat, poultry, and processed egg products in identifying ways to strengthen their biosecurity protection. FSIS recognizes that inspected plants may also be aware of, and may be adopting, guidelines from other government and private sector organizations and agencies.

FSIS designed "Food Defense Guidelines for Slaughter and Processing Establishments" to meet the particular needs of meat and poultry establishments and processed egg products plants. These guidelines are available on the FSIS Web site at http://www.fsis.usda.gov/Food_Defense & Emergency Response/FSIS Security Guid elines_for_Food_Processors.

While the guidelines are voluntary, and establishments may choose to adopt measures suggested by many different sources, it is vital that all food businesses take steps to ensure the security of their operations. Video surveillance equipment can be used to meet many different and varied food defense concerns. Establishments may not cover every element of their Food Defense Plan with video cameras and may choose short, moderate, or long recording durations. A common use of video surveillance is

monitoring the exterior of the buildings and premises to enhance the perimeter security of the establishment.

Videos or other electronic monitoring or recordings used by establishments for food defense purposes to maintain active monitoring and surveillance of process points of highest concern (vulnerable nodes) in food systems represent a credible countermeasure against intentional contamination. Providing FSIS access to the videos regarding food defense activities is voluntary, unless the video includes information relevant to an official investigation, such as a suspected case of food tampering. In those situations, FSIS may request access to all applicable establishment records. If in the future, the Agency decides to propose mandatory development and implementation of functional food defense plans, access to video records is one of the issues that FSIS will consider in the rulemaking.

VI. Use of Video or Other Electronic Monitoring or Recording Equipment to Meet HACCP and Sanitation SOP Recordkeeping Regulatory Requirements or for Other Purposes.

Establishments are required to keep records related to their HACCP plan, including all decision-making with its operation (i.e., monitoring, verification, and corrective action). This documentation includes the results of any testing and of any monitoring or verification activities, such as in prerequisite programs that are performed by the establishment that may have an impact on the establishment's hazard analysis, whether or not such testing or monitoring is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered as separate activities. Records of these activities, that may have an impact on the establishment's hazard analysis, as well as designated HACCP records, are subject to FSIS review and are to be available to FSIS personnel (9 CFR 417.5 (e) and (f)).

Establishments are required to develop and maintain a recordkeeping system that documents the monitoring of the critical control points (CCPs) (9 CFR 417.2(c) (6)). Establishments need to decide in advance how they will document their monitoring of and verification activities for their CCPs. If an establishment determines and designates a video or other electronic monitoring or recording equipment to record the required HACCP information, this information is to be included as part of its recordkeeping system description.

Accessibility of electronic or digital records is the same as for any other record, and establishments will need to comply with the applicable regulatory requirements for record retention and availability (9 CFR 320, 416.16, and 417.5). Establishments would need to provide appropriate methods or means for FSIS to view the video or digital records used for the purposes listed in 9 CFR Part 320.

The regulations (9 CFR 417.4(a) (2)) require ongoing verification activities, including the review of records generated and maintained in accordance with 417.5(a) (3). FSIS

would not anticipate that establishments can use video recordings to accomplish the purposes of 9 CFR 417.4(a) (2) (i) or (iii). However, an establishment may use video or other electronic monitoring or recording equipment as an ongoing verification activity by direct observation of the monitoring activities (9 CFR 417.4(a) (2) (ii). If the establishment does so, it must have documents supporting the verification procedures and frequency of using the video for this purpose. This documentation would include support that the video or other electronic monitoring or recording equipment captures all of the observable activities at the CCP. For example, if a recording, observed at a remote location, is used instead of physically walking to the monitoring point and observing the person, as they perform the monitoring procedures, then the establishment would have to demonstrate that the information and data recorded are accurate and that no food safety issues are missed.

Recordkeeping requirements in 9 CFR 417.5(a) (3) include monitoring and verification procedures and their results, as well as the initials or signature of the individual making the entry, the time and date of entry, and the product identification (e.g. name, code, lot). For example, initials or signature of an individual might be achieved by a time stamp on the video corresponding to a specific company employee with specific access to that record.

Establishments will also need to conduct activities designed to determine whether their automated recordkeeping systems are functioning as intended and to conduct verification activities on these systems. For video or other electronic monitoring or recording equipment, this means that the establishment will need to consider factors discussed in Section A "Systems Used for Creating Video or Other Electronic Monitoring or Recording Records."

The Sanitation SOP regulations (9 CFR 416.16 (a) (b)) require maintaining daily records to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data. Establishments need to decide in advance how they are going to document Sanitation SOP implementation and monitoring activities, such as observing performance of sanitation tasks and identifying noncompliance.

Establishments that designate and choose to use video records to meet Sanitation SOP regulatory requirements need to ensure that the video or other electronic monitoring or recording equipment they use meets the regulatory requirements of 9 CFR 416.16, that is, showing that the video records document the monitoring of the Sanitation SOP and any corrective actions that were taken. The establishment would need to determine how noncompliance would be identified, and what corrective actions it would need to take to restore sanitary operating conditions.

If a video record is to be generated in addition to a paper monitoring or verification record, establishments should determine in advance and designate whether they plan to rely on the video recording or other electronic monitoring or recording or the paper

record to meet regulatory requirements. Once the establishment designates the records from this type of equipment then the records would be available to the establishment and to FSIS, as are other records, according to 9 CFR 320, 416, and 417, for verification purposes.

Establishments may choose to submit non-HACCP, non-Sanitation SOP, or other management or surveillance video records to appeal a decision in a Noncompliance Record (NR). The validity of those records would be determined on a case-by-case basis. For example, an electronic surveillance record may demonstrate that monitoring of the CCP took place, but the results of the monitoring were not recorded. Establishments should be aware that all information on video or other electronic equipment records used in an appeal may be considered by FSIS in making a final appeal decision.

A. Systems Used for Creating Video or Other Electronic Monitoring or Recording Records

When video or other electronic monitoring or recording equipment is used to produce records that meet regulatory requirements, an establishment needs to design, maintain, and validate its system so that the records generated will be trustworthy, accurate, and a true representation of the process. In the absence of controls, electronic records can be easily manipulated. For example, FSIS would consider the absence of a record showing who has accessed a computer system, and what operations he or she has performed during a given period of time (audit trail) to be highly significant if there are data or record entry discrepancies. Similarly, lack of operational system checks to ensure that the correct order of manufacturing steps occurs (event sequencing) would be significant if such a deviation results in an adulterated or misbranded product.

FSIS recommends that establishments consider the following factors and design elements when establishing this type of recordkeeping system:

- 1. A recordkeeping system involving video or other electronic monitoring or recording equipment should be compatible with commercial industry standards and allow migration to new technologies and standards. For example, data generated on an older software system should be moveable to a newer version software file format, which enables the user to easily view a clear and complete copy that is legible or what is called "human readable" during the required record retention period for the applicable record. (See Section B "Maintenance and Retention of Records Generated Using Video or Other Electronic Monitoring or Recording Equipment.")
- 2. A recordkeeping system involving video or other electronic monitoring or recording equipment that is designated as a record to meet HACCP or Sanitation SOPs should be based on consideration of the following elements:
 - Access: Access to record systems should be limited to authorized individuals.

- Accurate copy: Systems should be able to generate accurate and complete copies of records in human readable and electronic form suitable for inspection and review.
- Audit trail: Systems should use secure, computer-generated, time-stamped audit
 trails to independently record the date and time of operator entries and actions
 that create, modify, or delete electronic records. Record changes should not
 obscure, previously recorded information. Audit trail information should be
 retained throughout the record retention period and be available for review and
 copying. The system needs to be designed so that sufficient information is
 retained to facilitate audits and resolve disputes.
- Authority checks: Systems should have a protocol or mechanism in place to
 ensure that only authorized individuals can use the system, electronically sign a
 record, access the operation or computer system, alter a record, or perform a
 required operation; and, there should be a means to ensure that the protocol or
 mechanism is rigorously followed in order to preserve original information and
 signatures reliably.
- Education: Persons who develop, maintain, or use electronic record and signature systems should have the education, training, and experience to perform their assigned tasks.
- Operator entry checks: Systems should include some mechanism that determines and records the validity of the source of any data entered manually. Appropriate controls over systems documentation should be established.
- Policies: Establishments should establish and adhere to written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures. Establishments need to set standards for how data is entered and recorded by automated systems.
- Protection: Systems should contain an adequate means to protect records for accurate and ready retrieval throughout the record retention period, including maintaining appropriate backup records.
- System checks: Systems should allow use of operational checks to enforce permitted sequencing of steps and events.
- Systems documentation: Systems should have adequate controls over the
 distribution of, access to, and use of documentation for system operation and
 maintenance. Revision and change control procedures should be in place to
 maintain an audit trail that documents the development and modification of
 systems documentation.

• *Validation*: Systems should be validated to ensure that they are accurate, reliable, consistent, and able to discern invalid or altered records.

<u>Note</u>: If an establishment contracts with a vendor to provide video or other electronic services, the vendor would need to meet or exceed the defined requirements of the components described above.

Establishments should validate their electronic/computerized systems. 9 CFR 417.4(a) (1) states, "Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities." Consequently, establishments should consider the impact that the system itself might have on the accuracy, reliability, integrity, availability, and authenticity of all required records. FSIS recommends that an establishments base its approach upon a risk assessment and a determination of the potential of the system itself to affect product safety and record integrity.

Some establishments may have an existing system in place. If that system does not meet the criteria noted above, then that system would likely need to be upgraded to address adequately the system components noted above.

B. Maintenance and Retention of Records Generated Using Video or Other Electronic Monitoring or Recording Equipment

FSIS believes that it is important to understand the factors unique to the maintenance of electronic records that need to be controlled to use the record. When needed, establishments should be able to accurately and readily retrieve and use the recorded information. Accessibility of electronic or digital information should follow established industry guidance, and establishments will need to comply with all applicable regulatory requirements for record retention and availability (9 CFR 320, 416.16 and 417.5). FSIS regulations in 9 CFR 320 contain basic requirements for records, including record retention time and types of records such as bills of lading, production records, invoices, shipping and receiving records, and related business records.

The following principles and practices provide guidance for the industry to meet this objective:

- Establishments should employ procedures and identify controls for the protection of records that permit their accurate and ready retrieval throughout the records retention period.
- Establishments should update their documented procedures and controls as they make changes.
- 3. Establishments should identify and control factors that could affect the reliability of electronic records during their retention periods.

Procedures should describe and include the following factors:

- How will the video surveillance or other electronic records be maintained?
- How is the data encoded within an electronic record (e.g., computer readable representations of information)?
- On what type of media (e.g., disk, tape, or flash memory devices) will the data be recorded?
- What hardware will be used to retrieve and display the electronic record?
- What software (both application programs and operating systems) will be used to read, process, and display electronic records?
- What are the storage conditions under which the records will be maintained?
- What environmental precautions are needed to maintain data (controlled environment)?
- What retrieval and access restrictions are there for data stored and maintained in electronic record storage (e.g., if personnel or software programs change or are upgraded can the stored data still be accessed)?
- Which personnel are responsible for maintaining the records?
- What processes are necessary to extract and present the information in human readable form?

If these factors are not controlled properly, then the information that the electronic records convey might not be complete, accurate, or usable.