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Draft 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 draft guide while pursuing 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 is requesting comments through the **Federal Register** on this information collection. Until the Agency receives OMB approval for the information collection, the draft guide should be viewed as not authoritative. Once FSIS receives OMB approval, it will issue the final guide. At that time, FSIS may also make changes to the guide based on comments received on this draft guide.

Table of Contents

I. Purpose

This document provides guidance to industry on the use of video or other electronic monitoring or recording equipment for monitoring operations and facilities for various purposes, including monitoring product inventory, conducting surveillance of establishment premises in a voluntary food defense plan, using a systematic approach to ensure that livestock are handled humanely, or ensuring that poultry good commercial practices are followed. Video or other electronic monitoring or recording equipment may also be used to meet FSIS regulatory record requirements. This document includes recommendations rather than regulatory requirements

FSIS is providing this **guidance** to make establishments aware that video or other electronic monitoring or recording equipment can be used in federally inspected establishments. FSIS encourages establishments to consider the use of this technology, particularly in their activities to ensure that there is humane handling of livestock and use of good commercial practices in poultry.

This guidance also informs establishments of the Agency's expectations if they decide to use this type of equipment to create records to meet regulatory requirements for HACCP or Sanitation SSOP. This guidance also provides information on the implications when an establishment uses this equipment for any other purpose, such as part of a systematic approach to ensure that livestock are handled humanely, or 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 food safety and record keeping requirements, video or other electronic monitoring or recording equipment cannot be used in a manner to harass, intimidate or interfere with FSIS Inspection Program Personnel (IPP) in the performance of their duties.

This guidance document is being issued following the procedures for guidance documents in the OMB's "Final Bulletin for Agency Good Guidance Practices." More information on OMB's policies and procedures can be found on the FSIS webpage: www.fsis.usda.gov/Significant_Guidance/index.asp .

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The document will be updated in response to comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov . Follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2-2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5474, Beltsville, MD 20705-5474.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2010-0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

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 1990's, traditional video technology was analog-based and was used for simple surveillance of premises with a closed circuit TV camera and a video cassette recorder (VCR). The video preserved information (or evidence), and the tape could be reviewed for what happened, after the fact.

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 integrate with other systems or with multiple locations; it can encrypt data, retrieve data from remote locations, and add software that enhances or manipulates images or otherwise directs video surveillance to detect specific criteria. 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 to monitor from a remote location to determine whether the selected activities or procedures are indeed taking place

These types of systems, from early traditional to fully digital, are a form 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.[1]

[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

However, “live feed video” from a surveillance camera would not be a record if it is not recorded or maintained.

Based on authorities under the Federal Meat Inspection Act (FMIA) (21 USC 642), Poultry Products Inspection Act (PPIA (21 USC 460(b)), and Egg Products Act (21 USC 1040), FSIS has allowed the use of industry video or electronic monitoring or recordings, in particular surveillance equipment, to meet certain aspects of recordkeeping under HACCP (9 CFR 417.5(d)) and Sanitation SOP (9 CFR 416.16 (b)) monitoring requirements. It has also allowed video and camera recordings to be used by establishments appealing a noncompliance record (NR). The Agency has interpreted the language in the regulations (“maintained on computers”) to include video records as well as a scanned copy of a PDF document or certain other electronic records.

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 can substitute for paper and handwritten records and are subject to statutory and regulatory requirements. As with paper records, video or other electronic monitoring or recording records can be designated as a record to meet HACCP and Sanitation SOP requirements or can be used for other purposes, such as Food Defense plans. Records not designated for HACCP or SSOPs, are not subject to 9 CFR Parts 416 or 417 recordkeeping regulations; however, FSIS may request access to all applicable establishment records if any food safety concerns are identified. For example, if potential product tampering has been detected, FSIS may request access to an establishment’s recordings of 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 (21 USC 1040) contain broad authority requiring certain classes of persons, firms, and corporations in the meat, poultry, and 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 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.

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accessible, and storage devices, such as CD jukeboxes or hierarchical storage management (HSM) systems.

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 maintaining humane handling or good commercial practices to comply with regulatory and statutory requirements. Video or other electronic monitoring or recording equipment could provide an establishment with continuous information on what is occurring at all times with humane handling at the establishment, freeing the establishment from having to rely on spot checks. Also, the possibility of multi-dimensional views of an establishment's processes with these technologies can bring together information that bears on 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 use to improve process control. The information gathered can also be used by establishments to train their employees.

Another type of video or other electronic monitoring or recording equipment that can be used to verify humane handling or good commercial practices is a remote video audit (RVA), which can integrate other establishment systems or multiple locations. This system can encrypt data and retrieve data from remote locations and can incorporate software that enhances or manipulates images. The system can use direct video surveillance to monitor and assess specific factors that the establishment is measuring. Some monitoring can be purchased as a service, with the vendor providing timely reports of daily auditing, predicting future problems, and systems analysis.

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 involves four steps[2] [i]to ensure that there is an integrated approach to humanely handling the animals and good commercial practices in poultry. The four 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.

[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).

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. Evaluating periodically how poultry are being handled and slaughtered to ensure that any excitement, discomfort, or accidental injury is minimized.

4. Improve or adjust operations in livestock to minimize the excitement, discomfort, or possibility of accidental injury. In poultry, improve or adjust operations if problems are found in the first three steps to ensure that excitement, discomfort, and accidental injury is minimized the entire time that live birds are held in connection with slaughter.

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 do monitoring in live areas to determine whether employees are taking actions to minimize excitement, discomfort, and accidental injury to the birds as they are hanging them 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 it is required to do. Assessing consciousness of animals involves observing, sometimes touching, the animal's eyes, or other parts, and viewing the animal from several visual perspectives.

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, they 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 on a memorandum of interview (MOI) if the event is not directly observed.

NOTE: IPP are not to focus on the "live feed video". While the 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 around the establishment than to simply 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 Federal and State inspected establishments that produce meat, poultry, and 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.

The guidelines that FSIS has developed are designed to meet the particular needs of meat and poultry establishments and egg products plants.
http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/FSIS_Security_Guidelines_for_Food_Processors/index.asp

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. For example, video surveillance can be used to monitor 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 vulnerable nodes (or process points of highest concern) 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 food safety or to a suspected case of tampering or food terrorism. 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 the agency will need to 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 Other Purposes.

Under the HACCP regulations, an establishment is required to keep records related to its HACCP plan, including all decision making with its operation (i.e., monitoring,

verification, and corrective action). Given these regulatory requirements for documentation associated with the plan's operation (e.g., monitoring, verification, and corrective action) the results of any testing and of any monitoring or verification activities that are performed by the establishment 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.

Therefore, records of these activities, that may impact 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)]. Examples of such results and records include, but are not limited to, all records, results, and supporting documentation associated with each HACCP plan; records, results, and supporting documentation associated with prerequisite programs; results and records of testing conducted for the establishment's business customers; and results and records associated with establishment's quality control or food defense programs or as part of its systematic approach to meet regulatory requirements for livestock humane handling and poultry good commercial practices.

The HACCP regulations require that establishments "*Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring* (9 CFR 417.2(c) (6))." Establishments need to decide in advance how they are going to document their monitoring and verification activities of their critical control points (CCPs). If an establishment determines and designates that a video or other electronic monitoring or recording equipment will be used to record the required HACCP information, this information is to be included as part of its description of its recordkeeping system.

Accessibility of electronic or digital information 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). The 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. Establishments would need to provide appropriate methods or means for FSIS to review the video or digital recording records used for the purposes listed in 9 CFR Part 320.

The regulations (9 CFR 417.4(a) (2)) also require "*Ongoing verification activities.* – which include but are not limited to*: (i) Calibration of process-monitoring instruments*, *(ii) Direct observations of monitoring activities and corrective actions; and (iii) 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 for direct observation of the monitoring. If it does so, it must have documents supporting the verification procedures and frequency of using the video for this purpose. This documentation would include

the establishment being able to support that the video or other electronic monitoring or recording equipment captures all of the activities at the CCP that a person could observe. For example, if a recording, observed at a remote location, is used instead of physically walking to the monitoring point and observing the display panel, 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). These records would be part of pre-shipment review and should be retained for the required period of time specified in 9 CFR 417.5 (c) and (e). 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") of this document.

The Sanitation SOP regulations (9 CFR 416.16 (a) (b)) state that "(a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. . . (b) 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, each establishment needs to show 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 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 occur (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*: Written policies should be established and adhered to 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.

Note: 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 establishments base their approach on 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 adequately address 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:

1. Establishments should employ procedures and identify controls for the protection of records that permit their accurate and ready retrieval throughout the records retention period.
2. Establishments should update their 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)?
- What type of media (e.g., disk, tape, or flash memory devices) will the data be recorded on?
- 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)?
- What 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.

VII. References:

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