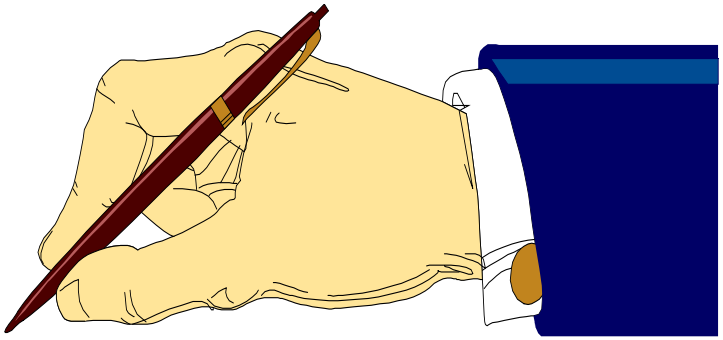
Module 24. Electronic Records and Signatures

Thermal Processing for Meat and Poultry Products Training

USDA

Legal Status of Electronic Records and Signatures

- Electronic records and signatures are considered the legal equivalents of paper records and handwritten signatures executed on paper.



Predicate Rules

- A predicate rule is any regulation or law that includes a requirement to keep a record.
- Look to predicate rule for
  - what records to keep
  - how long to maintain records
  - what signatures are required

Electronic Record

- An **electronic record** is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature

- An **electronic signature** is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

System Requirements: Validation

- Has the system been validated?
  - Expect to test off-the-shelf systems where source code is not available
  - Expect full software validation for systems developed in-house or where source code is available

System Requirements: Validation

Confirmation and examination of objective evidence that systems conform to user needs and intended uses and that particular requirements implemented by a system can be consistently fulfilled.

System Qualifications

- Installation qualification—meets codes and design specifications
- Operational qualification—operates consistently within established limits and tolerances
- Performance qualification—test the system to assure that it functions as intended.
  - This can be in the form of a series of challenges to make sure what is expected occurs.

Audit Trail

- Does the system generate a secure, time stamped audit trail for each electronic record?
- Does the audit trail show when a record was created, modified and deleted, and by whom and without obscuring previously recorded information?

Electronic Signatures

- Electronic signature mechanisms may be based on:
  - *biometrics* such as scan of retina, face or fingerprint, or voice recognition
  - *two distinct components* such as identification code or card and password

Electronic Signatures

- If a system employs biometric-based electronic signatures, is it designed so the signature mechanism cannot be used by anyone other than the genuine owner?

Electronic Signatures

- If system employs non-biometric signature mechanism, is the system designed so that
  - electronic signature mechanism can be used only by genuine owner?
  - attempted use by anyone other than genuine owner requires collaboration by two or more individuals (sharing cards)?

Electronic Signatures

- Is the system designed to:
  - allow the first of a series of signings during one continuous period?
  - allow signings during separate periods of access?
  - require use of all components of electronic signature mechanism?

Electronic Signatures

- Are electronic signature mechanisms:
  - unique to each individual signer?
  - not reusable by or re-assignable to anyone else?
  - linked to records, so they cannot be removed, copied, or transferred so as to falsify the record?

Electronic Signatures

- Do signed electronic records contain
  - printed name of signer?
  - date and time signature was executed?
  - meaning of signature (*e.g.*, authorship, review, or approval)?
- Is signature information readable in electronic display and printout?

System Checks

- Do operational system checks enforce sequencing of steps and events?
- Do authority checks ensure only authorized individuals can use system?
- Do device (*e.g.* terminal) checks determine validity of source of data input or operational instruction?

Record Availability

- Can the system generate complete and accurate copies in both human readable and electronic form?
- Are records protected to enable accurate and ready retrieval throughout record retention period?

Closed System

- **Closed system** means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

Open System

- **Open system** means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.
- Does the open system employ additional measures such as document encryption to ensure record authenticity, integrity, and confidentiality?

Assigning Electronic Signatures

- Is the identity of an individual verified before assigning an electronic signature?
- Does the manufacturer assure the electronic signature is unique to the individual and not reused or reassigned?
- Does the manufacturer assure that no two individuals have the same identification code and password?

ID Code/Password Control & Maintenance

- Are identification codes and passwords periodically checked, recalled, or revised?
- Are transaction safeguards in place to prevent unauthorized use of passwords and/or identification cards?
- Is system access limited to authorized individuals?

ID Code/Password Control & Maintenance

- For systems employing tokens or cards with identification codes or passwords:
  - Are tokens or cards tested initially and periodically?
  - Are loss management procedures in place and followed for missing or compromised cards or tokens?

Training, Policies, & Procedures

- Do those who develop, maintain, and use the system have the necessary education, training, and experience?
- Have policies been established to deter record and signature falsification?
- Have employees been trained in these policies?

System Documentation

- Is documentation of system operation and maintenance controlled and made accessible only to those who “need to know?”
- Are there revision and change control procedures to maintain an audit trail regarding systems documentation?

Example Electronic Retort Log

THERMAL PROCESSING TRAINING

Event Log Report Header For FMC FoodTech Customer	Approved By : Jane Smith On 04/24/2007 16:58:34 PM

Recp #	Recipe Description	RecipeCode	Container Size	Process Time	Process Temp	Initial Temp	Start Date & Time	End Date & Time
216	Special Drink	216	16 oz Ball	00:04:49	251.0 °F	35.00	04/23/2007 14:11:20	04/23/2007 15:00:02

Controller #: 1 Cycle #: 4 Process Date: 4/23/2007 Print Date: 4/15/2008 Print Time: 16:38:14

Log Type	Time	Phase	Log Description	Elapsed	Entry	TEMP	PRESS	RTD-2	RTD-4	Flow	Level %	RPM
	14:11:20	SensChck	Begin Sensor Checks	00:00:00		98.71	0.0	104.10	98.33	0	9	0.00
	14:11:23	SensChck	End Sensor Checks	00:00:02		98.65	0.0	104.11	98.30	0	9	0.00
	14:11:23	SensChck	File version 0.0.0.19 - Date 03-06-2007	00:00:02		98.84	0.0	104.07	98.30	0	9	0.00
	14:11:23	Greetings	Begin Hot Well Setup	00:00:00		98.66	0.0	104.09	98.30	0	9	0.00
	14:14:01	Oper Entry	Begin Operator Entry Phase	00:00:00		98.72	0.0	102.79	98.23	0	9	0.00
	14:14:09	Oper Entry	John Smith: Successfully Logged into Security	00:00:08		98.59	0.0	102.79	98.23	0	9	6.00
	14:14:18	Oper Entry	Recipe Number Selected:	00:00:16	216	98.58	0.0	102.75	98.23	0	9	6.00
	14:14:18	Oper Entry	Immer Cook Spray Cool	00:00:17		98.61	0.0	102.73	98.20	0	9	6.00
	14:14:21	Oper Entry	Alarm Acknowledged	00:00:19		98.60	0.0	102.69	98.22	0	9	0.00
	14:14:25	HtWl Setup	Begin Hot Well Setup	00:00:00		98.66	0.0	102.69	98.20	0	9	0.00
	14:15:00	Loading	Begin Loading	00:00:00		98.44	0.0	102.52	98.14	0	9	0.00
	14:16:59	Loading	Product Code	00:01:59	123-456	98.40	0.0	102.02	98.01	0	9	0.00
	14:17:00	Loading	Batch Code	00:01:59	TDFR123	98.46	0.0	102.06	97.99	0	9	0.00
	14:17:00	Loading	End Loading	00:01:59		98.46	0.0	102.06	97.99	0	9	0.00
	14:17:44	Vent	Begin Vent	00:00:00		97.96	2.8	108.95	97.45	0	9	1.60
	14:18:52	Vent	End Vent	00:01:07		268.76	28.0	234.06	268.22	1,496	62	18.30
	14:18:53	Come Up	Begin Segment 1	00:00:00		268.78	28.8	234.73	268.20	1,595	63	18.40
	14:22:16	Come Up	At Steam On Till Temp	00:03:24		240.04	27.2	243.62	239.59	1,542	63	18.40
	14:23:16	Come Up	PID Switched	00:04:24		252.91	29.8	255.26	252.40	1,398	65	18.40
	14:23:23	Come Up	Begin Segment 2	00:04:31		255.43	29.4	254.97	255.43	1,359	65	18.30
	14:23:54	Come Up	Begin Segment 3	00:05:02		254.95	30.6	253.21	254.12	1,429	65	18.40
	14:24:25	Come Up	Begin Segment 4	00:05:33		252.93	31.6	252.04	252.29	1,458	64	18.30
	14:24:46	Come Up	Begin Segment 5	00:05:54		253.03	32.0	251.30	252.28	1,453	62	18.40
	14:25:07	Come Up	Begin Segment 6	00:06:15		252.84	32.0	251.03	252.22	1,368	61	18.40
	14:25:38	Come Up	Begin Segment 7	00:06:45		253.03	32.1	251.08	252.33	1,404	62	18.40
	14:26:09	Come Up	End Come Up - Total C.U.T =	00:07:16	00:08:24	253.15	32.1	251.26	252.52	1,400	61	18.30
	14:26:10	Cook	Begin Cook	00:00:00		253.19	32.1	251.28	252.51	1,443	61	18.30
	14:27:19	Cook	Alarm Acknowledged	00:01:09		253.49	32.0	251.73	252.78	1,402	62	18.50
	14:27:37	Cook	John Smith: Successfully Logged into Security	00:01:27		253.56	32.0	251.79	252.77	1,417	62	18.40
	14:28:10	Cook	MIG Entry	00:01:59	253.5 F	253.30	32.0	251.84	252.75	1,290	62	18.30
	14:28:10	Cook	Chart Entry	00:02:00	253.0 F	253.49	32.0	251.85	252.72	1,266	62	18.30
	14:28:39	Cook	Start Heat Recovery	00:02:29		253.49	32.0	251.87	252.77	1,400	62	18.30
	14:30:59	Cook	End Cook Phase	00:04:49		251.51	31.9	250.50	250.82	1,164	36	18.40
	14:31:00	NumCool	Begin Segment 1	00:00:00		251.53	31.9	250.51	250.80	1,158	36	18.40
	14:31:52	NumCool	End Heat Recovery	00:00:53		242.29	31.5	229.88	241.32	852	22	18.40
	14:31:53	NumCool	Begin Hot Well Setup	00:00:53		242.29	31.5	229.88	241.32	852	22	18.40
	14:32:00	NumCool	Begin Segment 2	00:01:01		238.81	31.9	225.98	237.67	888	21	18.30

Paper vs. Electronic Records

- **Question:** Can electronic records be archived as paper printouts only?
- **Answer:** No. Records must be archived in electronic form, and the establishment must be able to generate electronic copies. Electronic records have meta data—date stamps, audit trails, and other information—not intended to be printed but important to audit.

Questions

Questions?