

February 6, 2018
USDA Agricultural Marketing Service
National Organic Program



#### **Topics**



2018 Audit Schedule

2018 Audit Priorities

## **Topics**



## **Audit Schedule**

Renewals

Midterm

decisional

Satellite Office

**Domestic (USA - Primary Office)** 

Compliance

Initial

DA

le		USE
	2018	

2018 Audit Schedule	
	2018

2018 Audit Schedule	
	2018

(Projected)

47

21

2017

**62** 

39

**Total Accreditation Audit Events** 

Document Adequacy Review and Pre-

03

3

16

21

**26** 

9

4

40

## **22**

## **Topics**



## **Audit Priorities**



#### **Audit Priorities are...**

- ✓ Guidance to NOP Auditors
- ✓ Issues identified by the NOP requiring certifier improvement
- ✓ Investigation of certifier implementation of and compliance to USDA organic regulations and policies



#### **Audit Priorities are not...**

✓ The only verification or reporting that must be accomplished during an audit



- On-site Inspections
- Ruminant Livestock
   Certification
- Satellite Offices





- § 205.403
  - (a) On-site Inspections
  - (b) Scheduling
  - (c) Verification of information
  - (d) Exit interview
  - (e) Documents to the inspected operation

- Inspector Instructions
- Risk Assessment Analysis
- Roles and Responsibilities
- Verification of the Organic System Plan
- Traceability and Quantitative Analysis (i.e. Trace-Back and Mass Balance inspection tests).
- Recordkeeping
- Use of the Regulations and NOP Policies



#### **Inspector Instructions**

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- Are certifiers providing general and specific guidance to inspectors for each inspection? Such as specific items to verify, sampling instructions, collection of records, specific issues, etc...
- Are inspectors required to report back to certifiers about specific points or tasks?
   Are those points or tasks noted in the inspection report or another document?



## **Risk Assessment Analysis**

- Have inspectors reviewed the materials given to them?
- Have inspectors assessed what are the potential risks to organic integrity?



## **Roles and Responsibilities**

- Who is responsible for maintaining compliance?
- Are inspectors providing operators a description or clarification of the roles and responsibilities of operators, inspectors, and certifiers?



#### **Verification of Organic System Plan**

205.403(c)(2) states "That the information, including the organic production or handling system plan....accurately reflects the practices used or to be used.....by the applicant or certified operation"

 Are certifier inspector training, inspector instructions, OSP templates, inspection checklists, and inspection reports designed to facilitate verification reporting?



Would you expect to see this statement on an OSP or Inspection Report?

Buffer hay harvest equipment is cleaned and documented in the field activity journal. Buffer hay is given to brother for conventional livestock.



Buffer hay harvest equipment is cleaned and documented in the field activity journal. Buffer hay is given to brother for conventional livestock.

OSP updated at inspection, see attached.

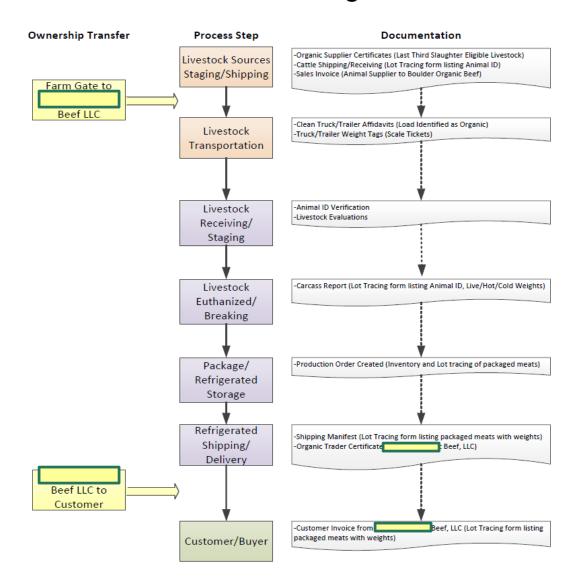


## Recordkeeping

- Identification of Operation Records Used and maintained in an OSP
- An example document showing a combination of Title (Ownership), Production/Handling Flow, and identification of Records in an OSP

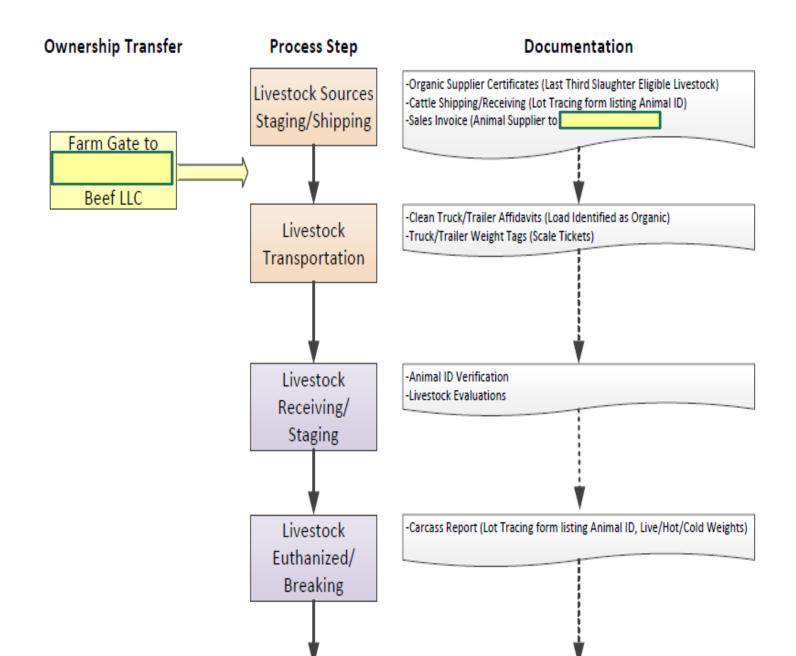
SECTION 8: Record Keeping System		NOP Rule 205.103	
NOP Rule requires that records disclose all activic compliance with the NOP Rule. Organic products records must be accessible to the inspector for re-	must be tracked back to the field/location w	here they were produced/harvested. All	
A. RECORDS: Please have these records a	available for the inspector.		
Which of the following records do you ke	ep for organic production?		
☐ field maps			
field activity log(s)			
field history sheets (previous three ye	ars)		
documentation of previous land use for	or rented and/or newly purchased land		
-	eds, manure, foliar sprays, and pest co	ontrol products (keep all labels)	
documentation of attempts to source	organic seeds and/or planting stock		
documentation of organic seedlings			
residue analyses of inputs (i.e., manu	re sourced off-farm)		
compost production records			
	ests, water tests, quality tests, observa	tions)	
equipment cleaning records	are data of horizont and horizont amount	ete (including quetem hamast records)	
	ers, date of harvest, and harvest amour	its (including custom harvest records)	
label records	cation and identification, field numbers,	amounts, and cloaning activities	
clean transport records	ation and identification, field numbers,	amounts, and cleaning activities	
	ct, invoice, cash receipts, cash receipt	iournal sales iournal etc.)	
shipping records (scale ticket, dump s		journal, sales journal, etc.)	
Transaction Certificates	nation tionot, bill of lauring,		
audit control summary			
complaint log			
other (please specify)			
Fo how long (years) do you keep your re	cords on site available for review?		
Which of the following records do you ke	eep for conventional production?	Not applicable, no conventional production	
☐ field maps	labor records	·	
field history sheets	storage records		
input records	sales records		
harvest records	shipping records		
other (specify)	· · ·		

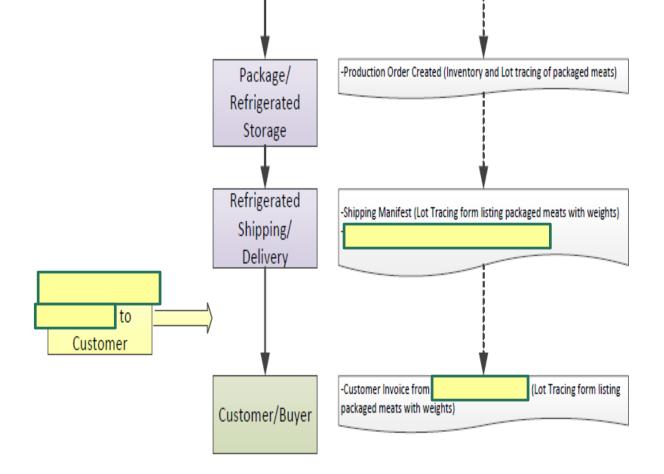
#### **Document Flow Diagram**

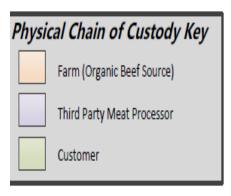




#### **Document Flow Diagram**









#### Use of the Regulations and NOP policies

- Do inspectors have <u>access to the</u> <u>regulations and policies</u> during the inspection?
- Are <u>inspectors discussing the regulations</u> with operators when issues are identified?
- If an issue of concern is identified, are inspectors confident that <u>operators</u> <u>understand and can find a regulation</u>?



#### **Traceability and Quantitative Analysis**

- Should occur at <u>all</u> inspections.
- There should be a section or annex in the inspectors report to <u>record the activities</u> in adequate detail for reviewers to understand.
- Traceability testing verifies records maintained and flow of ingredients and products through the system.
- Mass Balance testing. Are outputs reflective of the inputs used? Inspectors should justify why they selected a certain time frame and specific ingredients or products.

#### SAMPLE AUDIT WORKSHEET FOR Producer

I. Trace-back Audit Worksheet: Please choose <u>a title transfer document</u> (Invoice, BOL, or Shipping Document) for a finished organic product and trace it, or some of its ingredients back to the supplier(s) and date(s) of delivery of raw materials. List all documents necessary, and the connecting data elements between the documents that allow the finished product to be traced back to the incoming raw materials and their compliance documentation.

1. State product chosen	Organic Garbanzo Beans
2. Lot #, Date Code, or product tracking system code for the above product	2011
3. Describe the trail of documents	Product tracking could not be initially verified because garbanzo delivery records were not maintained. However, during the inspection some shipping records for the 2011 organic garbanzo beans were faxed to the office. A summary of a weight certificate follows:  Weight Certificate 6-30-2011,  Organic Garbanzo Beans, Fields 6,8.9

10.000				
4. Does the trace-back audit confirm that the facility has a complete audit trail, and is product being accurately tracked through the system?	Product tracking from outgoing shipment back to the certified organic field is satisfactory.  However, note that the shipping documents for last year's organic garbanzo bean crop were not maintained in the office so the buyer furnished a weight certificate representing one of the shipments. Note also that the weight certificate misidentified one of the fields. Field 9 is actually fallow, so the harvested yield was miss-attributed from another organic field on the ranch.			
5. Does the trace-back audit verify the accuracy of the for the product chosen?	The trace-back audit is consistent with the			
INSPECTOR SIGNATURE	DATE			

## Mass Balance Worksheet p.1

State Product/Ingredient Chosen	
If ingredient, state list of products containing this ingredient.	
3. State Time Period Chosen (Month, Quarter, Year)	
4. From Worksheet p.2 – Compare the Raw Material <u>Usage</u> to the Finished Goods <u>Production</u> .	
From Sales Records - Total Sales     Volume of product or ingredient found in all products containing this ingredient.	
5. <u>Calculated Sales from the Worksheet</u> <u>p2.</u> – Total volume of Product or ingredient found in the Calculated Sales of all products containing this ingredient.	
6. Comments	

Mass Balance W	orksheet	p.2	Ingredie	ent Selected			_
Raw Materials			Period S	Selected			_
				1 Beginning Ir (as of	nventory)		
				2 Purchases			
				3 Ending Inve	ntory)		
				1+2-3 = Usa			• .
				- <del>Sales per Sa</del>	ales Records		
Finished Goods		4					Total
	Product 1	1 % Ingredient	Product 2	2 % Ingredient	Product 3	3 % Ingredient	Ingredient Amount 1+2+3
1 Beginning Inventory (as of)							
2 Production ()						-	
3 Ending Inventory (as of)	-						
1+2-3 = Calculated Sales							
Sales per Sales Records							



## Other Areas of Interest for NOP Auditors:

- Unannounced inspections
- Residue sampling
- Broker/Trader inspections



## Ruminant Livestock Certification

#### **Ruminant Livestock Certification**



#### **Auditor focus:**

- Do Reviewers and Inspectors have the skills, knowledge, and experience to conduct livestock certification review and inspection?
- Are inspections conducted at appropriate times?
- Frequency of inspections is appropriate for the type of operation?
- Length of inspections is adequate to cover the complexities and scope of the operation?





#### What is a Satellite Office?

Global certifiers frequently <u>establish</u> <u>regional offices</u> in countries acting as a hub to conduct certification activities.

<u>These offices may conduct one or more key activities</u> (e.g. certification decisions, inspections, etc...).

#### **Key Activities**

- Policy formulation;
- Process and/or procedural development;
- Contract review;
- Application review;
- Inspection planning;
- Review, approval, and decision-making on the results of inspections;
- Adverse action decisions;
- Material, ingredient, and input review, approval and decision-making; and
- Label review, approval, and decision-making.



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#### What we know:

- Certifiers that operate outside the US typically have satellite offices
- In April 2016 NOP identified:
  - 28 of 79 certifiers had more than one location conducting NOP key activities
  - Of those 28 certifiers, there were a total of 41 other key locations



#### NOP 2000, 6.3, Onsite Review

"If the certifier operates satellite offices in addition to its main office, then all of its offices are assessed to ensure that sufficient objective information is collected to verify that the certifier's program quality manual system and NOP certification requirements are effectively implemented and requirements are met."

#### In Section 7,

"For certifiers with satellite offices, a witness inspection or a review audit will ultimately be conducted at each office."

#### **Considerations:**

- Satellite Offices are to be audited within the five year accreditation period.
- Audit preparation and execution are typically as rigorous for Satellite Office Audits as for renewal and midterm audits depending upon the functions and activities of the satellite office.
- For planning purposes: 2 3 days on-site to include at least one witness or review audit.

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- On-site Inspections
- Ruminant Livestock
   Certification
- Satellite Offices