

	Instruction for Verifying Compliance When On-Site Inspections are not Possible	Doc Nr	TI 74
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1. Purpose

This instruction to be followed for verifying compliance when on-site inspections are not possible. ETKO will develop case related measures to inform its personnel and the clients.

2. Scope

This instruction covers the measures to be taken against the **CORONA – COVID – 19** Pandemic. This instruction will be applied for the IACB- EU and NOP official program.

3. Responsibilities

This procedure is prepared and implemented by the Management and QMR which the other department responsible will be involved according to the decision of the management.

All ETKO staff members to read and understand the procedure to implement appropriately

4. Application

As the risk of COVID-19 continues to spread and travel restrictions, stay at home/shelter in place orders, and other restrictions develop, it has become challenging to conduct on-site organic inspections as usual while ensuring the safety of inspectors and clients.

For this reason, the following alternative ways will be followed to verify compliance in the COVID-19 outbreak process.

4.1. Risk-Based Approach to Prioritizing Existing Operations for Remote, Records, or Hybrid Inspection During COVID-19 Pandemic

Remote inspections and records audits will be used to verify compliance for existing operations; and will realize on-site inspections when it is safe to do so, using a risk-based approach as follows.

Risk assessment will be made to prioritize the order of on-site inspections when it is possible to realize on-site inspections. On-site inspections will be conducted when possible, with ETKO prioritizing follow-up on-site inspections at higher risk operations. And on-site inspections will be combine with robust remote records audits to reduce the amount of time needed for the on-site inspection.

4.1.1. Risk Assessment for Existing Operations - How to Prioritize Remote Inspections/Records Audits

The Risk Assessment Instruction created by ETKO will be applied to determine how to prioritize remote inspections and/or desk audits to ensure or verify continuous compliance.

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ETKO will take into consideration whether an operation is deemed low risk based on the Risk Assessment Instruction; has previous noncompliance; or has a physical operation that takes possession of or produces products.

In addition, it will be considered whether a certified operation in good standing has added land or facility to an existing certificate, or whether the certificates have been changed. Triage will be made based on time elapsed since the last on-site inspection, as well as seasonality (whether it is an appropriate time to conduct a remote inspection and see relevant activity).

An operation-by-operation risk assessment will be made to consider additional factors and concerns, areas of focus for the remote inspection and/or records audit, and any areas of focus for the eventual on-site inspection.

The risk assessment will be made for each operation be fully documented.

4.1.2. Risk Assessment for Existing Operations - How to Prioritize On-Site Inspections When Available

With the uncertainty of the COVID-19 pandemic, and attendant travel restrictions, stay at home orders, and shelter in place orders, it is possible that operations deemed low risk may not get on-site inspections in 2020.

When onsite inspections are available in a region, Risk Assessment Instruction will be used to determine how to prioritize on-site inspections to establish or verify the continued compliance.

ETKO will take into consideration whether the inspection is to verify corrective actions, investigate existing complaints, or verify additions to an existing certificate.

ETKO will also take into consideration whether an operation was able to conduct a remote inspection.

Triage will be made based on time elapsed since the last on-site inspection, as well as seasonality (whether it is an appropriate time to conduct an on-site inspection and see relevant activity).

An operation-by-operation risk assessment will be made to consider additional factors and concerns, areas of focus for the remote inspection and/or records audit, and any areas of focus for the eventual on-site inspection.

The risk assessment will be made for each operation be fully documented.

For new products, on-site inspection may not be required if new products are produced and handled on a certified operation following the existing, approved organic systems plan and a certification decision can be made based on document review alone. For other changes, risk-based approaches will be applied to determine if remote inspections will be sufficient to assess compliance.

The specific planned changes will be check with operator, to determine whether an inspection is required and if so, if a remote inspection would be sufficient.

On-site inspections will be robust, and will focus on any concerns identified or items not easily verified during remote audit, as well as the physical premises. Questions may be asked about compliance going back to the previous on-site inspection.

If these on-site inspections take place during the pandemic, local inspectors will be used who would not need to travel significantly.

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4.1.3. Risk Assessment for New Operations - How to Meet the On-Site Inspection Requirement During COVID-19 Pandemic

Certification decisions for new operations will be based (at least in part) on an on-site inspection.

In an effort to allow for continued certification of new operations when compliance can be verified, and doing so is in compliance with all relevant local, state, and federal restrictions and orders, the followings will be applied:

- Where limited on-site inspections are available - allowed under local, state, and federal restrictions or orders; as well as accepted by the inspector, operation, and ETKO; a hybrid approach will be made - implementing a brief and socially distanced on-site inspection (in which the operator is still verifying compliance, in accordance with all relevant social distancing norms, recommendations, and orders), along with a robust remote inspection and/or records audit.
- If on-site is not available in an area due to local, state, or federal restrictions or orders; or because it is not agreed to by any of the inspector, operation, or ETKO; then new operations may not be certified. In these cases, the remote inspection and records audit process will be beginning and the certification decision will be delayed until an on-site inspection has been performed. Technical assistance will be ensured to these operations regarding labeling and marketing options that are available to uncertified operations (such as using the term organic in the ingredient statement) in the interim.
- New operations will receive a high priority for on-site inspections when travel restrictions, stay at home, and shelter in place orders are lifted.
- If any of these on-site inspections take place during the pandemic, local inspectors will be used who would not need to travel significantly.

4.2. Remote Inspections

4.2.1 Deciding on Technology

Technologies will be chosen that support specific remote inspection needs.

Technologies will be considered that offer the functions that we need (live video, recorded video with date and GPS stamp, file sharing, screen sharing, etc.), are easily available to our operations and inspectors, and offer confidentiality and security protections (including end to end encryption) aligned with us and our operation’s needs.

Remote inspections will require internet or cell service, as well as hardware (such as a smartphone or tablet). If such is not available, an operation will need to rely on other alternatives.

4.2.2 Preparing for a Remote Inspection – Training

No remote inspection will take place unless both the inspector and the operation agree to its use.

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The inspector and the operation will agree outlining what technology will be used, date/time, and who will be expected to be present and able to use the technology. If the inspector wishes to record any part of the remote inspection, consent will be taken from the operator and all participating individuals first.

Additional training which is containing the following topics, will be made for inspectors and operations:

- Training on any technology platforms that the operator is expected to use.
- Specific training for conducting remote inspections will be realized for inspectors.

4.2.3 Process of Remote Inspection

Pre-Inspection Meeting: A pre-inspection meeting will be made. By the end of this meeting, an agreement will be signed between the inspector and the operation outlining what technology will be used, date/time, and who will be expected to be present and able to use the technology. This pre-meeting will be conducted using technologies that will be used in the remote inspection, to set the tone for the remote inspection. During this pre-inspection meeting, inspectors will share inspection objectives, scope, criteria, and methods - and how the inspector will assess compliance remotely.

Inspector will identify areas of interest and will ensure that the operation is prepared to demonstrate compliance in those areas (e.g., by walking to a particular field with the video chat, or recording a video tour).

At this time, the inspector will outline some best practices regarding teleconferencing - such as lighting, having materials ready, video on, limiting background noise.

The inspector will set the expectation that this may be a multi-day event, with significant back and forth and learning while doing (e.g., the inspector may come back and ask for more documents, more video, and another interview - if he or she feels necessary).

Interview: This will be conducted remotely using agreed-to video technology. It is important to ensure that the inspector and the operator are comfortable with the technology being used. It will be done using video technology, if possible, to ensure that non-verbal communication is captured. If video technology is not available or practical, a phone interview is acceptable.

Verify Documents and Records: This will be done live, via screen-sharing and video technology. The operation will send or share files electronically, screen-share, or physically mail documents. (If using physical mail, it will have a significant time lag, and there will need to be agreement on what to do with the physical documents afterwards.) The pre-inspection meeting will be outlined which documents must be shared, and the operation shares them in a timely manner.

This will be an opportunity to use this review of records as a window into operations on the operation, and to dig deeper on the processes and systems that we would otherwise see on-site. A deep review of documents and records, with extensive open-ended questioning, will provide good insight.

Records will be requested and reviewed/audited in advance so that the time required for the live portion will be shortened.

Records should be detailed and clear so that all activities and operations of the certified operation can be easily understood and controlled.

Count and Measure (physical examination): As part of operational tours and audits, inspectors regularly count, measure or observe quantities. This will be done through

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video and requested records, but inspectors and operations will need to be prepared for it to be more difficult and take more time.

Observe Tasks, Processes, Inputs, and Outputs: A physical view, tour, or observation of the operation will be made. A video tour of the operation with special focus will be made on certain areas, and extensive open-ended questioning. Inspectors will be prepared to specifically direct the operator where to point the camera - the smartphone will be the inspector’s eyes.

Brief and Socially Distanced On-Site Visits: If something cannot be verified any other way, and can only be verified by a brief and socially distanced on-site visit (in which the inspector is still verifying compliance, in accordance with all relevant social distancing norms, recommendations, and orders), that will be considered as a last resort - only if such behavior cannot be postponed, is necessary, is agreed to by both the inspector and operation, and complies with current travel restrictions, stay at home orders, shelter-in-place orders, and any other orders of the state or locality.

Exit Interview/Inspection Report: Exit interviews will include the fact that the inspection was remote. Inspection reports will include that fact as well, and will be very precise in their documentation of all specific details of how the inspection was conducted. This will include a list of what could not be verified, and an opinion about what needs to be verified on a follow-up on-site inspection, once restrictions are lifted.

4.3. Records Audit Alternative to a Remote Inspection for Technologically-Limited Operations

New operations will require an on-site component prior to certification. Brief and socially distanced on-site visits will be done (in which the operator is still verifying compliance, in accordance with all relevant social distancing norms, recommendations, and orders) that comply with all relevant travel restrictions, stay at home orders, shelter in place orders, and other orders.

In case of any operation that cannot avail himself of the technology needed to conduct a remote audit, the records audit will be made until on-site inspections become available.

4.3.1 Who Qualifies for a Records Audit?

Inspectors will conduct a records audit until travel restrictions are lifted for operations who cannot avail themselves of the technology needed for a remote audit (whether due to lack of hardware or lack of cellular or wireless service).

This will be applying for operations without remote connectivity or for operations which prohibit or severely limit the use of technology. For operations that have connectivity and do not prohibit or limit the use of technology, solutions such as borrowing technology from neighbors will be considered on a case-by-case basis.

Beyond this, a risk assessment will be used to determine what operations qualify for records audits. Lower-risk annual audits will be considered good candidates; new operations are not good candidates.

4.3.2 Preparing for a Records Audit

Records audits with limited technology will be difficult. Because of that, on-site inspection will be made to an operation inspected with a records audit.

Thus, a key outcome will be verifying what can be verified on the documents, and identifying specific areas for follow in an on-site inspection, when available.

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ETKO will contact the operation and will indicate that a records audit will be conducted. And ETKO will explain what that is and how to prepare.

ETKO will work closely with inspectors who have experience with particular operations or communities to develop specific plans for a pre-inspection meeting during which a set of records and paperwork is requested in advance of the records audit.

ETKO and inspectors will consider the cultural gap between operators and policy, and the inspector will be empowered to use his or her expertise to ask for what is needed in a way the operation will understand.

What specific records?

- Focus on what is feasible to verify based on documents, and request those documents.
- Base this on areas of interest in the operation's Organic Systems Plan, and previous inspection reports and exit interviews.
- Focus on continuous improvement, and accept that there will be topics that cannot be verified, and on which the inspector will have to focus at the next on-site inspection.
- Document clearly what was asked for, what was received, what is a top priority for follow up on-site.

Appropriate records will be determined by the certifier and inspector. Some records that might be particularly easy to request (and use for verification) include, but are not limited to:

Crops	Handling
Seed invoices	Current SOPs
Seed search records (if non-organic seed purchased)	Receiving logs
Field records (planting, input applications, etc.)	Pest logs
Harvest records	Sales records
Storage records	Batch records
Sales records	Organic certificates for purchased ingredients and other traceability records to verify that organic ingredients came from a certified source.
Shipping records	Inventory records

How to send?

- File sharing, email, fax, mail, or other contactless sharing - understanding that mail takes longer, and it will be critical for the operation to have its own copy of the records during the telephonic records audit.

Once the records are received and reviewed, the inspector will conduct a telephone call with the operation to go over the records.

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4.3.3 Process of a Records Audit

Pre-Inspection Meeting: ETKO will contact the operation and indicate that a records audit will be conducted, what that is, and how to prepare (including having access to a telephone). ETKO will work closely with inspectors who have experience with particular operations or communities to develop specific plans for a pre-inspection meeting during which a set of records and paperwork is requested in advance of the records audit. ETKO and inspectors will consider the cultural gap between operators and policy. And the inspector will be empowered to use his or her expertise to ask for what is needed in a way the operation will understand.

Interview: This will be conducted remotely using the telephone.

Verify Documents and Records: The pre-inspection meeting will outline which documents must be shared, and the operation will share them in a timely manner. This will be an opportunity to use this review of records as a window into operations on the operation, and to dig deeper on the processes and systems that we would otherwise see on-site. Following that review, a phone conversation will be made between the operation and the inspector, in which both have access to the documents, during which questions can be asked and concerns resolved. A deep review of documents and records, with extensive open-ended questioning, will provide good insight.

Count and Measure (physical examination): As part of operational tours and audits, inspectors regularly count, measure or observe quantities. This will be done through requested records, but inspectors and operations will need to be prepared for it to be more difficult and take more time.

Exit Interview/Inspection Report: Exit interviews will include the fact that the inspection was a records audit. Inspection reports will include that fact as well, and will be very precise in their documentation of all specific details of how the inspection was conducted. This will include a list of what could not be verified, and an opinion about what needs to be verified on a follow-up on-site inspection, once restrictions are lifted.

4.3.4 Brief and Socially Distanced On-Site Inspection as Last Resort

If something cannot be verified any other way, and can only be verified by a brief and socially distanced on-site visit (in which the operator is still verifying compliance, in accordance with all relevant social distancing norms, recommendations, and orders), that will be considered as a last resort - only if such behavior cannot be postponed, is necessary, is agreed to by both the inspector and operation, and complies with current travel restrictions, stay at home orders, shelter-in-place orders, and any other orders of the state or locality.

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