Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Animal Indicator Approval and Revocation Framework

Livestock Identification and Traceability Program

Version 6

2018-01-26

Canada

Document history

Version	Date	Comment
0		Pre-launch versions of the framework document saved under RDIMS #2564129
1	2012-08-30	First version of the framework document Sections highlighted in grey are draft proposals
2	2012-10-15	- Modification to section 5.20 - Modification to Annex D, points 6 and 7 - Addition of section E10 - Modification to annex F; specific requirements for air coil based and ferrite core based indicators - Modification to section H2
3	2013-05-24	- Inclusion of cost considerations in impact analyses (section 7.2) Removal of the following tests from section E: - Direct test to measure insertion force - Insertion force required for coupling using test jig - ISO 527-1 standard. Plastics -- Determination of tensile properties -- Part 1: General principles. - IEC 60068-2-14; Thermal change test: -40°C to +85°C - IEC 60068-2-1; Cold test: -40°C for 48 hours; -25°C for 24 hours - IEC 60068-2-2; Dry Heat test: +70°C for 48 hours; +55°C for 24 hours - IEC 60068-2-18; Damp heat 40°C at 93% relative humidity for 21 days exposure - ISO 175: 2010. Plastics - Methods of test for the determination of the effects of immersion in liquid chemicals - ISO 9352 - Abrasion test - ISO 175: 1999 - Immersion test
4	2014-10-16	- Alberta Agriculture and Rural development removed from the Foreword (as requested) - Amendment to section 5.1, indicating that approved indicators may, under specific circumstances, bear a herd mark instead of an identification number unique to the animal following the ISO 11784 standard - Minor amendments to sections 5.7, 5.11 and 5.14

		- Replacement of "logo" by "trademark" throughout the document - Amendment to the definition of "administrator" - Amendment to section 6.1, indicating that field trials could be replaced by the collection of observations on the performance of indicators for species not yet subject to federal traceability requirements - References have been updated - A definition of "herd mark" was added - Clarification under section 8.4, annexes D and E that indicators must be kept at test temperature for at least two hours before being tested in laboratories. - Removal of sections E6 (mechanical and thermal robustness test), E7 (endurance test) and E8 (ultra-violet resistance)
5	2015-11-19	- Amendment to section 5.1, indicating that under special consideration, a manufacturer's code could be used instead of a country code as a part of an animal identification number that follows the ISO 11874 standard - Amendment to maximum insertion force standard (section E2) - Amendment to tensile strength standard (section E4) - Amendment to annex F
6	2018-01-26	- Amendments to annex E - Amendments to annex F - Listing and defining animal species subject to traceability requirements - Addition of a contact for the pig sector - Amendment to Figure 4

Modifications to the last version of the document are double-underlined.

Executive Summary

The National Animal Indicator Approval and Revocation Framework (the Framework) is a technical document that is targeted toward manufacturers of indicators. The document will ensure that there is a minimum standard of conformance and performance of livestock indicators used by responsible administrators within the Canadian traceability system. The document outlines in detail the technical requirements necessary for the successful submission, testing and approval of indicators for use in Canada's livestock identification and traceability program.

The Framework uses the International Committee on Animal Recording (ICAR) standard as the basis for submission for testing. ICAR approval is the threshold for an application for approval. Testing is broken down into three areas for new indicators and two areas for indicators which are approved and currently participate in the program.

New submissions

New submissions for the approval of indicators must go through a series of laboratory tests at an accredited institution. Tests are conducted to ensure that the indicators meet electrical, mechanical, and physical standards described in the Framework. All standards are internationally recognized with performance standards ascribed that recognize the physical environments they will be subjected to in Canada. Once tested and having met the performance standards, indicators must meet the requirements of a field trial. All indicators must pass a field trial conducted in Canada. Indicators must also pass separate field trials for each species of livestock they will be applied to. The trial will be carried out under the scrutiny of the responsible administrator and be reviewed by NIDMAC before achieving national approval.

Modifications

Approved indicators submitted with modifications are evaluated differently. Tests conducted are based upon the changes made to the approved indicator. Factors affecting retention characteristics (weight, morphology, locking mechanism, stud configuration, material) will require a new field trial to determine if the modifications have negatively impacted the retention of the approved indicator. Factors affecting electrical performance characteristics (RFID inlay, antenna, microchip, capacitor etc.) will require electrical as well as performance testing to determine if the modifications meet the minimum requirements for performance as outlined in the Framework.

Manufacturers will be able to test their indicators against the National standard and be assured that responsible administrators will use standardized protocols and performance measurements to evaluate the indicator while on test. The increased performance standards and enhanced testing will greatly enhance the quality of future indicators in the program.

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Foreword

Under Part XV of the *Health of Animals Regulations* administered by the Canadian Food Inspection Agency (CFIA), animals must be identified with an approved indicator before leaving their farm of origin. This requirement is a key element of traceability in support of mitigating the impacts from a sanitary issue originating from and/or affecting the Canadian herd, and from natural disasters.

This Animal Indicator Approval and Revocation Framework provides information on the approval and revocation process and on the performance requirements against which they will be evaluated. A transparent, science-based approval process will enhance the quality of indicators being approved, and consequently support traceability and compliance to traceability requirements.

This Framework was developed by the members of the National Identification and Methodology Advisory Committee (NIDMAC) representing the following organizations and governments:

Agriculture and Agri-Food Canada
Agri-Traçabilité Québec
Canadian Bison Association
Canadian Cattle Identification Agency
Canadian Cervid Alliance
Canadian Food Inspection Agency
Canadian National Goat Federation
Canadian Pork Council
Canadian Sheep Federation
Dairy Farmers of Canada
Equine Canada
Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec

The Canadian Food inspection Agency would like to thank those organizations for their contribution.

1. Context

1.1. Traceability is the "ability to trace an item, whether it be an animal, plant, food product, or ingredient, from one point in the supply chain to another, either backwards or forwards" (ISO/DIS 22005).

1.2. The main objectives of livestock traceability in Canada are to (a) reduce the impacts of a disease outbreak, food safety issue or natural disaster originating from and/or affecting the Canadian livestock; (b) better protect public and animal health, and; (c) enhance the sustainability of the Canadian livestock sector.

1.3. There are three main components or pillars to agriculture and food traceability: (a) the identification of animals, animal products or food, (b) an event related to the animals, animal products or food (e.g. departure from a site), and (c) the identification, characterization and location of a site ('establishment' under OIE definition) where animals, animal products or food have transited.

1.4. Federal identification and movement recording and reporting requirements for livestock are covered under Part XV of the CFIA-administered *Health of Animals Regulations* (hereafter referred to as the Regulations).

1.5. The assessment of animal indicators[1] is performed on the basis of the criteria outlined in section 173 of the Regulations. Animal indicators used under the national Livestock Identification and Traceability program are approved and revoked by the Federal Minister of Agriculture and Agri-Food (hereafter referred to as the Minister).

1.6. Under the authority provided under subsection 13(3) of the *Canadian Food Inspection Agency Act*, the National Manager of Animal Identification Programs of the Canadian Food Inspection Agency (CFIA) (hereafter referred to as the National Manager) has been designated responsible for approving and revoking indicators.

1.7. The animal species subject to the Regulations and for which indicators must be approved are: bison, bovine, ovine, and pig. The document hereunder also supports the approval of indicators for caprine and cervid expected to be subject to traceability requirements through regulatory amendment.

[1] In this document, "animal indicators" refers to tags or any other type of identification means

2. Vision, objectives and scope

2.1. The vision is for a transparent, scientifically rigorous, and traceability conformance- and performance-oriented animal indicator approval and revocation process.

2.2. The main objectives of the approval and revocation process are:

a) To support traceability objectives and performance criteria;
b) To limit issues related to indicator conformance and performance;
c) To enhance communications as to which indicators have been approved or revoked;
d) To ensure all key stakeholders have had the opportunity to comment as to whether an indicator should be approved or revoked;
e) To ensure that impacts from approving or revoking indicators are well understood and communicated to all key stakeholders, and;
f) To harmonize test procedures, and identification technologies and methodologies whenever possible.

2.3. The main objectives of this Framework are to clarify:

a) The roles and responsibilities of partners involved in the manufacturing, approval and revocation of indicators;
b) The approval and revocation process for indicators;
c) The tests that shall be conducted on proposed new indicators;
d) The identification technologies and methodologies currently approved;
e) The approval process for new identification technologies and methodologies;
f) The performance standards and requirements against which indicators will be measured against, and;
g) The means by which the performance of indicators is measured.

2.4. This Framework provides information for the identification technology and methodology approved at a given time. It will be amended in the event new identification technology or methodology is approved.

2.5. The evaluation of transceivers is not covered in this document.

2.6. <u>The document hereunder supports the approval of secondary indicators where required to be applied to animals under the Regulations (the application of a secondary indicator is proposed for cervid). However, the document does not support the approval of secondary indicators applied voluntarily or required under provincial regulations.</u>

3. Roles and responsibilities

3.1. The manufacturers are responsible:

- To inform the responsible administrator at least six months in advance on their intent to modify approved indicators they produce;
- To seek approval of changes made to approved indicators;
- To ensure the continuous supply of approved tag to regulated parties;
- To make available all the necessary material and pay for field and laboratory trials to be conducted;
- In the event that an indicator is approved, to provide the National Manager the information identified under Annex J;
- To provide to the responsible administrator and the National Manager, the guidelines on how to properly apply and read the indicator;
- To work with the responsible administrator and CFIA to address issues identified in the field trial process, and;
- To inform the responsible administrator at least three months in advance that an indicator will no longer be produced or distributed.

3.2. The responsible administrators[2] are responsible:

- To test or cause to test indicators submitted for approval or revocation based on the protocol described in the Framework;
- To inform the National Manager and the NIDMAC of all requests made for an indicator, methodology or technology to be approved or revoked;
- To review proposals for the approval or revocation of indicators and test results submitted to their attention against the Framework and, if applicable, raise issues or concerns with the proponent. The administrator will only receive proposals for species it is responsible for;
- To submit proposals and test results to the CFIA;
- To provide recommendations to the National Manager as to whether the indicator, methodology or technology should be approved or revoked for the species they administer on the basis of the criteria outlined in section 173 of the Regulations;
- To support the conduct of an impact analyses when required under the Framework;
- To conduct annual evaluations on the indicators approved (see Annex I);

[2] See glossary for definition. The Canadian Cattle Identification Agency (CCIA) is recognized as the administrator responsible for the bison, bovine and ovine components of the livestock identification and traceability program; whereas the Canadian Pork Council is the administrator responsible for pigs. The CFIA also received and considered tag approval and revoking recommendations provided by Agri-Traçabilité Québec (ATQ), the Canadian Sheep Federation and the National Livestock Identification for Dairy (NLID).

- In co-operation with the CFIA, to communicate to the regulated parties
  - the list of indicators that are approved or have been revoked
  - proper methodology for application of approved devices, and;
- To set a process where issues about approved indicators may be communicated and addressed.

3.3. The National Identification and Methodology Advisory Committee (NIDMAC) is responsible to:

- Recommend to the CFIA an Animal Indicator Approval and Revocation Framework, including:
  - national performance and conformance standards against which the indicators will be evaluated
  - field and laboratory tests through which indicators will be evaluated
  - a review process for proposed new technologies or methodologies;
- Recommend to the CFIA livestock identification policies that are acceptable to all stakeholders and meet the national identification and traceability standards;
- Develop common national position on draft international livestock identification standards and policies, and;
- Review the impacts in the approval of a new livestock identification technology or methodology (see section 7).

3.4. The National Manager of the Livestock Identification and Traceability Program at the Canadian Food Inspection Agency (CFIA) is responsible:

- In consultation with stakeholders, to develop, communicate and update as required the Framework;
- To communicate and keep up-to-date, the list and description of indicators that have been approved and revoked;
- To review and initiate investigation of any issues identified with already approved animal indicators such as animal health concerns, and/or performance issues;
- To review recommendations from responsible administrators on which indicators should be approved or revoked, and;
- To approve and revoke indicators under the Livestock Identification and Traceability Program on the basis of the criteria outlined in section 173 of the Regulations.

4. Identification technologies and methodologies currently approved

4.1. The type of identification technologies currently approved for animal species subject to the Regulations are as follows:

Bison, bovine, ovine, pigs

- Non-electronic, visually read, plastic ear indicator;
- Non-electronic, visually read, metal ear indicator;
- Ear indicator with ISO 11785-based RFID transponder (half-duplex technology, HDX), and;
- Ear indicator with ISO 11785-based RFID transponder (full-duplex technology, FDX-B).

Pigs kept primarily for research purposes, entertainment purposes or for a person's company

- Microchip sub-cutaneous implant.

4.2. Indicators are approved on a per species basis.

4.3. The following identification methodologies approved under the program are:

Bison, bovine, ovine, pigs

- Indicator applied to the ear of animals.

Pigs kept primarily for research purposes, entertainment purposes or for a person's company

- Sub-cutaneous implant

Pigs received at an abattoir

- Shoulder slap tattoo

Note: a request is expected for the approval of leg band for caprine as a new identification methodology.

5. Performance and conformance standards; and objectives

Conformance standard

5.1. All indicators shall bear a unique identification number per the ISO 11784 Standard using the country code for Canada (i.e. '124' for Canada). Under special consideration, a manufacturer's code could be used instead of a country code (e.g. for non-farm animals). Moreover, the identification number on the indicator could correspond to a herd mark instead of an ISO number.

Performance standards

The following performance standards shall be met when the corresponding evaluation identified in the annexes has been completed.

5.2. 100% of the indicators will be tamper evident.

5.3. At least 99.5% of the identification numbers on the devices will be easily and reliably readable.

5.4. The retention of indicators applied to ears will be at least 99% after the short-term or at least 98% after the standard field trial.

5.5. The evaluation results for any test conducted under this Framework will be analyzed and reported at a 95% confidence level. The sample size selected for any test should be sufficiently large so as to ensure the marginal error to be within 5%, that is, the characteristic being tested can be estimated within a 5% level of accuracy.

5.6. At least 98% of the indicators will be successfully installed without failure.

Performance objectives

5.7. The indicator is difficult to counterfeit (e.g. reproduce an official indicator or alter the identification number of the indicator).

Visual requirements of approved ear tags

5.8. The ear tag is external and visible.

5.9. Printing on all ear tags will be in highly-contrasted colour.

5.10. All printing will be indelible and permanent.

5.11. The identification number of the ear tag will be printed on the female part of two piece tags and along the length of the exposed portion of one piece tags.

In order to improve legibility, the identification number of ear tags approved for pigs will be printed on the male part of two-piece tags.

The identification number will be a herd mark or meet the ISO 11784 standard and therefore be composed of 15 digits. The approved tags bearing an identification number using the ISO standard with only the last nine digits on the female part or along the length of the exposed portion of one piece tags (whereby the responsible administrator trademark replaced the country code and "000") remain approved (unless performance issues are identified) but will gradually being phased-out of the program. The 15 or last nine digits of the identification number will be printed on the male part of two piece tags.

5.12. Following the ISO 11784 standard, a national identification code is included between bit 27 and 64. The first three digits of the national identification code is managed by the CFIA and may correspond to systems where animal identification numbers were allocated, animal breeds, etc. The last nine digits of the national identification code is unique to an animal. A range of animal identification numbers has been provided by the CFIA for each main livestock sector.

5.13. The size of characters and trademark must be a minimum of 4 mm in height, creating a minimum visible reading distance of 75 cm (Reference: ICAR standard).

5.14. The responsible administrator's trademark will be printed on all approved ear tags. For two piece tags, the trademark will be printed on the front facing, exposed female portion of the ear tag and on the exposed portion of the backing stud (male part). In order to improve legibility, the responsible administrator's trademark will be printed on the male part of two piece tags approved for pigs.

The approved tags not bearing the trademark on the male part are grandfathered.

5.15. Additional trademarks or markings are permitted upon National Manager written approval only.

Supplementary requirements for electronic approved ear tags

5.16. An ear tag approved after an electrical modification to previously approved ear tag (see annex D) will be visually distinct from the latter.

5.17. All transponder models submitted for approval must be approved by ICAR. The responsible administrator will not consider transponder models that are undergoing ICAR certification. Only ICAR registered manufacturers may submit indicators for testing/approval within the Canadian system.

5.18. The animal identification number printed on the indicator shall correspond to the one displayed when the transponder is scanned.

5.19. Each transponder must be one-time-programmable (OTP).

5.20. At least 99% of approved indicators shall be machine-readable for a minimum of seven years following their application on animals under typical field conditions. Transponder failure must not exceed 0.5% over the first three years.

6. General approval process of an indicator from a technology or methodology already approved under the program

6.1. The evaluation of an indicator is required in the event that:

- A request is made for the approval of a new indicator
- Performance issues have been identified with this given indicator
- Modifications are made to the approved indicator.

A list of indicators approved for species expected to be subject to the Regulations needs to be made available to regulated parties before the regulations come into force. If there is a demonstration in Canada that indicators used voluntarily or mandated through provincial regulations meet the requirements specified hereunder, field trials as described under this document will not be required for these new species.

6.2. The responsible administrator and/or the National Manager may decide to re-evaluate approved indicators if performance issues have been raised.

6.3. In the event modifications are expected to be made to approved indicators, the manufacturer will be required to inform the responsible administrator about such change at least six months in advance, and apply for approval. The indicator will still require to be approved under ICAR.

6.4. Laboratory tests do not need to be performed in the event an animal indicator already approved for a species is recommended for another species. However, a standard field retention trial will need to be conducted.

6.5. A request for an indicator to be (re-)evaluated must be submitted to and agreed beforehand by the responsible administrator(s). The responsible administrator may refuse the request to test a new indicator based on the criteria outlined in section 173 of the Regulations.

6.6. The proponent will submit an evaluation submission form (Annex C) to the responsible administrator(s) for review against the Framework. Only ICAR-registered manufacturers may be proponents under the Framework.

6.7. The responsible administrator(s) may suggest indicators to be tested, the location of the field trial, and the production model through which the indicators would be tested.

6.8. The responsible administrator(s) will use the indicator approval process flow chart (Annex B) to determine the appropriate test path for the indicator.

6.9. The responsible administrator(s) will provide the evaluation submission form to the CFIA for review and to the NIDMAC for information.

6.10. In the event no issue has been identified with the evaluation submission form, the trials will be conducted following the guidelines provided under the Framework. Otherwise, the National Manager will inform the responsible administrator and the proponent about which modification(s) to the protocol submitted are required.

6.11. The proponent will submit final results of the evaluations to the responsible administrator(s) for their review against the Framework. In the event of a standard field trial (see Annex H, H2), preliminary results will also be provided half-way through the study. Preliminary results do not need to be provided for a short term field trial (see Annex H, H1).

6.12. The responsible administrator(s) will submit test results and provide recommendations to the National Manager as to whether the indicators being tested should be approved, not approved or revoked.

6.13. The National Manager will make a decision based on the criteria outlined in section 173 of the Regulations, and the conformance and performance standards identified under this Framework document. The discretion of the decision-maker cannot be fettered by the NIDMAC or the responsible administrator(s).

6.14. The National Manager will communicate the decision to the responsible administrator(s) and NIDMAC. The responsible administrator will communicate the decision to the proponent.

6.15. If applicable, the National Manager will send a revised list of approved and/or revoked indicators to stakeholders.

6.16. A service standard of 30 days is expected from the time the results of an evaluation are submitted to the National Manager and a decision is being made.

7. Approval process of a new technology or methodology

7.1. In the event that an identification technology or methodology different from the one that is currently approved is being proposed (see section 4), the proponent will first seek interest from NIDMAC. Any person may be a proponent for a new methodology or technology.

7.2. In co-operation with the administrator responsible for the species where such technology or methodology would be used, otherwise NIDMAC, the proponent will be responsible for conducting an impact analysis.

7.3. The impact analysis will include at a minimum the following items:

- Legibility
  - Interoperability, compatibility with transceivers currently used under the national livestock identification and traceability program
  - Interoperability, compatibility with identification technology, methodology accepted at the time by our trading partners
  - Issues for software to receive and transmit the number of an animal identified from this new technology or methodology
  - Issues for databases to receive and store the number of an animal identified from this new technology or methodology
  - Logistical issues for veterinarians, inspectors and operators of commingling sites (e.g. abattoirs, auctions) to read and report the number of an animal identified from this new technology or methodology
- Unique identification number
  - Support the unique identification of animals or a group of animals
- Costs
  - Indicators from new technology or methodology
  - Replacement and/or addition of this new technology or methodology under the program
  - Readers

- Disposal of carcasses identified with such technology or methodology.

7.4. The impact analysis will be performed for the environment(s) where the new technology or methodology would be used.

7.5. Only one impact analysis will be required for each new type of identification technology or methodology being proposed (the technologies and methodologies currently approved are listed under section 4).

7.6. The impact analysis will be reviewed by the responsible administrator, and NIDMAC. The NIDMAC will provide a recommendation to the National Manager on whether the new technology or methodology should be approved. The impact of maintaining *status quo* will need to be considered by NIDMAC in its recommendation.

7.7. The decision to approve a new technology or methodology will be made by the CFIA.

7.8. Indicators from a new approved technology will undergo the approval process as outlined under section 6. Any studies conducted to support the impact analysis could be used to support the approval of indicators from this technology if such studies meet the guidelines identified in this Framework.

8. Animal indicator testing requirements

8.1. The person or organization conducting the tests will have sufficient qualifications and not be in a conflict of interest i.e. would not draw personal benefits from the approval or revocation of indicators.

8.2. Performance testing of devices will occur in both the laboratory and in the field. Tests will provide results of how animal indicators will work in on-farm situations. These include mechanical, physical, material and electrical tests.

Laboratory testing

8.3. All conformance testing will be performed by a test laboratory accredited by the International Committee on Animal Recording (ICAR).

8.4. Conformance testing will be based on the ISO 24631-1 Standard and conducted at the following approved testing temperatures: -35°C, +20°C, and +40°C. Indicators will be stabilized at the test temperature for two hours prior to the test.

8.5. Laboratory performance evaluation will be based on ISO 24631-3 Standard.

8.6. Electrical, mechanical, performance, material, and retention tests as outlined in the Framework are required for all previously unapproved indicators or approved indicators that have undergone changes as determined by the responsible administrator with consultation to the Framework.

8.7. An electrical test (Annex D) is required on approved indicators that have had changes made to the electrical components of the device such as silicon die, antenna, or capacitor.

8.8. A mechanical test (Annex E) is required on approved indicators that have had changes made to the male stud portion, tamper evident area, the attachment mechanism, or material composition.

8.9. An indicator read-range performance verification (Annex F) is conducted after any and all other tests have been completed.

8.10. Morphological changes to an approved indicator (e.g. shape, size) will be tested as indicated under Annex G.

Field testing

8.11. A field trial will be required with all new indicator approvals as well as approvals for modified approved indicators where changes have affected key areas such as device weight, attachment mechanism, male stud, device dimension or morphology (see Annex H).

9. Revocation process

9.1. A request for an indicator to be revoked may be made by the responsible administrator or an organization representing the interest of parties subject to traceability requirements.

9.2. An indicator may be revoked based on the criteria outlined in section 173 of the Regulations.

9.3. The request for revocation must be submitted to the responsible administrator(s).

9.4. The responsible administrator(s) will communicate with the manufacturer of indicators to assess if the issue identified may be resolved without moving forward with the revocation process.

9.5. If the responsible administrator(s) agrees that the indicator should be revoked, a recommendation will be made to the National Manager for decision.

9.6. In the event any concern is identified with an indicator, the National Manager may unilaterally decide to revoke the indicator after discussing the matter with the responsible administrator and the manufacturer.

9.7. The National Manager will review the recommendation based on the criteria outlined in section 173 of the Regulations and against the performance and conformance standards specified in the Framework document.

9.8. In the event the National Manager agrees with the recommendation, steps to reduce the prevalence of the indicator in the herd/flock will be taken, including:

a) responsible administrator(s) to stop the allocation of these indicators
b) manufacturers and distributors to stop producing and distributing those indicators as approved
c) custodians of livestock to be informed about the decision and encouraged of phasing-out the usage of those indicators
d) inspectors monitoring the prevalence of these indicators at sites such as abattoirs, auctions.

9.9. The prevalence of the indicators being observed at abattoirs and/or auctions should be less than 10% before the indicator is revoked by the National Manager.

9.10. The National Manager will communicate the decision to the responsible administrator(s), and send a revised list of revoked indicators to stakeholders.

10. Performance measurement

10.1. Manufacturers of indicators shall have an auditable quality control program.

10.2. The responsible administrator will conduct quality control evaluations of approved animal indicators for criteria outlined in section 173 of the Regulations.

10.3. Evaluations conducted at distribution centres will follow the protocol under Annex I, Figure 4.

10.4. Evaluations conducted throughout the manufacturing chain will follow the protocol under Annex I, Figures 4 and 5.

10.5. The responsible administrator will notify the applicable manufacturer and the NIDMAC of any evaluation results. Based on the nature and result of evaluation, the responsible administrator may recommend to the National Manager the revocation of the indicator.

10.6. Responsible administrators will set a process by which complaints on the performance of approved tags are received and reviewed. If complaints are made to manufacturers about animal indicators or applicators, the manufacturers will inform the responsible administrator within five (5) working days on the nature of those complaints and proposed corrective actions.

References

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Annex A. Acronyms and Glossary

Acronyms

CFIA	Canadian Food Inspection Agency
FDX	Full duplex
FPT	Federal, Provincial and Territorial
HDX	Half duplex
ICAR	International Committee for Animal Recording
ISO	International Organization for Standardization
OIE	World Animal Health Organization
psi	pounds per square inch
RFID	Radio-frequency identification
rH	relative humidity
TTT	Traceability Task Team
UV	ultra-violet

Glossary

Approved indicator *(identificateur approuvé)*: An animal indicator approved by the Federal Minister of Agriculture under subsection 173(1) of the *Health of Animals Regulations* and listed on the web site of the CFIA as an approved indicator.

Bison *(bison):* An animal, other than an embryo or a fertilized egg, of the subspecies *Bison bison bison*, *Bison bison athabascae* or *Bison bison bonasus*

Bovine *(bovin):* An animal, other than an embryo or a fertilized egg, of the species *Bos taurus* or *Bos indicus.*

Caprine *(caprin)*: An animal, other than an embryo or a fertilized egg, of the genus *Capra.*

Cervid *(cervidé)*: An animal, other than an embryo or a fertilized egg, of the family *Cervidae.*

Country code *(code de pays)*: Bit pattern to define the country where the transponder was issued (ISO 11784 standard). The three-digit numeric code representing the name of a country is in accordance with ISO 3166-1 numeric standard.

Electrical Test *(essai électrique)*: Laboratory tests performed on indicators seeking approval which measure conformance and performance of the indicator against the NIDMAC standards. See Annex D

Evaluation *(évaluation)*: Periodic assessment of efficiency, performance, relevance and impact of a project in the context of stated objectives (Reference: Codex Alimentarius).

Full duplex *(duplex intégral)*: Method of information exchange in which the information is communicated while the transceiver transmits the activation field (Reference: ISO 11785 standard).

Half duplex *(semi-duplex)*: Method of information exchange in which the information is communicated after the transceiver has stopped transmitting the activation field (Reference: ISO 11785 standard).

Herd mark *(marque de troupeau)*: The identification number unique to a group of animals originating from the same site.

Mechanical Test *(essai mécanique)*: Laboratory tests performed on indicators seeking approval which measure conformance and performance of the indicator against the NIDMAC standards. See Annex E.

Ovine *(ovin):* An animal, other than an embryo or a fertilized egg, of the genus *Ovis.*

Pig *(porc):* An animal, other than an embryo or a fertilized egg, of the genus *Sus.*

Radio frequency identification *(identification par radiofréquence)*: An indicator that uses radio frequency technology. The RFID device or method of identification includes ear indicators, boluses, implants (injected), and indicator attachments (transponders applied during the tagging process).

Regulated parties *(parties réglementées)*: Every person who owns or has the possession, care or control of an animal as defined under Part XV of the federal *Health of Animals Regulations.*

Responsible administrator *(administrateur responsable)*: a person, an organization who is authorized by the Minister of Agriculture and Agri-Food Canada to receive information in relation to animals or things to which the Health of Animals Act or Regulations apply, is listed on the CFIA's web site as an administrator and administers a national identification program in relation to certain animals of all or part of one or more genera, species or subspecies that are located in one or more provinces. *For the purpose of this document, an administrator also covers a national agricultural producer group.*

Secondary indicator *(indicateur secondaire)*: Indicator applied in addition to and bearing the same identification number as the primary, approved indicator.

Tag allocation *(attribution de numéros d'identification)*: The allocation by an administrator to a manufacturer of identification numbers to be printed or inscribed onto approved tags.

Tamper-proof/tamper-evident *(inviolable)*: Tamper-evident devices reveal any signs of adjustment, removal, or re-application. Tamper-evident devices may not be reapplied to a second animal.

Transceiver (*émetteur-récepteur)*: Device used to communicate with a transponder (Reference: ISO 11784 standard).

Transponder *(transpondeur)*: Device which transmits its stored information when activated by a transceiver and may be able to store new information (Reference: ISO 11784 standard).

Annex A1. Contact information

Bovine sector

Canadian Cattle Identification Agency
Paul Laronde: plaronde@canadaid.ca

Agri-Traçabilité Québec
Lyne Ravary: lravary@atq.qc.ca

Dairy Farmers of Canada
Mélissa Lalonde: mlalonde@atq.qc.ca

National Livestock identification for dairy (NLID)
Linda Markle: lmarkle@holstein.ca

Bison sector

Canadian Bison Association
Terry Kremeniuk: cba2@sasktel.net

Ovine sector

Canadian Sheep Federation
Corlena Patterson: corlena@cansheep.ca

Agri-Traçabilité Québec
Lyne Ravary: lravary@atq.qc.ca

Pig sector

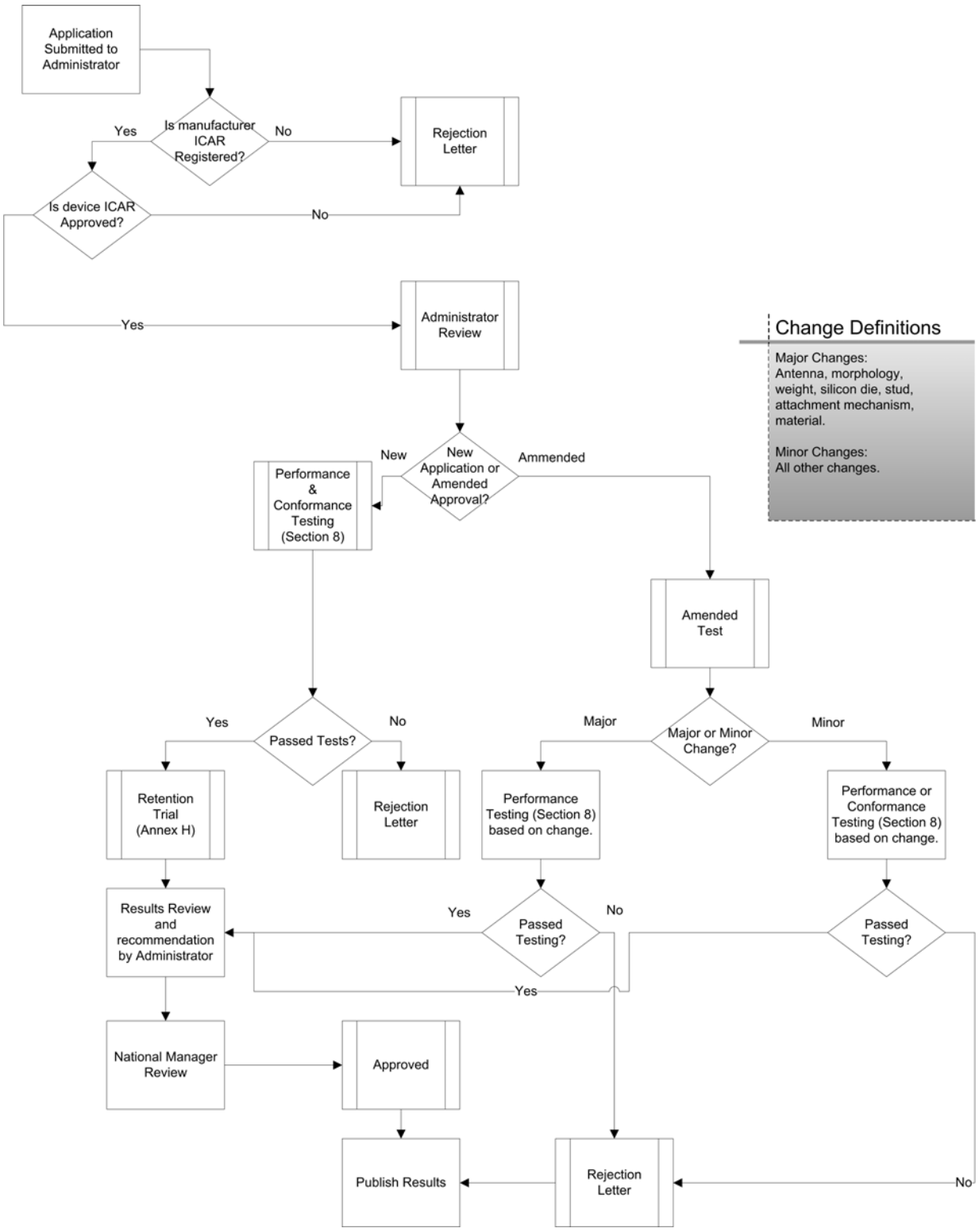
Canadian Pork Council
Jeff Clark: clark@cpc-ccp.com

Canadian Food Inspection Agency

Eric Aubin: eric.aubin@inspection.gc.ca
Elizabeth Corrigan: elizabeth.corrigan@inspection.gc.ca

Annex B. Indicator approval process

Figure 1. General approval process for indicators (RDIMS #10295506)



Annex C. Evaluation submission form

Information on the proponent					
Name					
Organization					
Contact information					
Information on the person, organization performing the evaluation					
Name					
Organization					
Contact information					
Experience, qualifications					
Information on the indicator being evaluated					
Status of the indicator	Approved		Revoked		
	Not approved				
Type of evaluation	New assessment				
	Review				
	Evaluation from electrical modification of approved indicator				
	Evaluation from physical modification of approved indicator				
Type of indicator	Non-electronic RFID, plastic ear tag				
	Non-electronic RFID, plastic tag				
	Non-electronic RFID, metal tag				
	RFID HDX ear tag				
	RFID FDX-B ear tag				
	Other, specify:				
General technical description					
Manufacturer					
Information on potential users					
Species for which such indicator is/would be used	Bovine				
	Bison				
	Ovine				
	Pigs				
	Cervid				
	Caprine				

	Equid	
Organization(s) supporting the evaluation		
Information on evaluation		
Objectives		
General description		
Milestones and timelines		
Financial support		
Literature review		
References		
Information on evaluation – supplementary information for field trials		
Number and location of the test sites		
Environmental factors (e.g. production model, pasture conditions, containment, housing, restraint method)		
Statistical design		

Annex D. Electrical Testing Requirements

Test using ISO standards 24631-1 and 24631-3

Electrical Testing:

1. Indicators must conform to ISO 11784/85
2. Indicators will be tested in an ICAR approved test centre to ISO standards 24631-1 and 24631-3.
3. Five (5) transponders of 50 supplied will be tested
4. Test Conditions:
    a. Temperature: -35°C, +20°C, +40°C. Indicators will be stabilized at the test temperature for two hours prior to the test.
    b. Humidity: 40% – 80% rH
    c. Noise: <30 dBuV/m (band width 2.7hHz)
5. Transponder orientation:
    a. Air coil: parallel to transmitting antenna plane
    b. Ferrite core: perpendicular to transmitting antenna plane
6. Minimal activating magnetic field strength in FDX-B mode shall be activated by a magnetic field strength of no more than 0.6 A/m, measured according to ISO Standard 24631-3, section 7.6.4. “Minimal activating magnetic field strength in FDX-B mode” and will develop a modulation amplitude equal to 10 mV, measured according to ISO Standard 24631-3, 7.6.6, "Modulation amplitude in FDX-B mode", by a magnetic field strength of no more than 0.6 A/m.
7. Minimal activating magnetic field strength in HDX mode will be activated by a magnetic field strength of no more than 0.6 A/m, measured according to ISO Standard 24631-3, section 7.6.5, “Minimal activating magnetic field strength in HDX mode”, and will develop a modulation amplitude equal to 10 mV, measured according to ISO Standard 24631-3, section 7.6.7, "Modulation amplitude in HDX Mode", by a magnetic field strength of no more than 0.6 A/m

After each test, device is subjected to visual inspection, functional verification, and performance check.

Visual inspection after each test shall confirm the integrity of the indicator and the absence of plastic deformation.

Functional verifications during and/or after each test shall confirm the integrity of the electronic identification code.

Annex E. Mechanical Testing Requirements

Testing must demonstrate that the ear indicator cannot be removed and reapplied without obvious evidence that this action has occurred. Reusable indicators will not be accepted.

E1. Insertion force with applicator indicated by the manufacturer for use with the tag.

This test measures the insertion force needed to couple the male and female portion of ten (10) indicators at each of the following temperatures and relative humidity:

-35°C ± 2°C	50% rH ± 5%
+20°C ± 2°C	50% rH ± 5%
+40°C ± 2°C	50% rH ± 5%

Indicators will be stabilized at the test temperature and relative humidity for two hours prior to the test. The test will be performed using the assigned applicator.

The manufacturer's recommended applicator is inserted to allow the indicators to be coupled when force is applied at the mid-point between the pivot point and the end of the applicator handles. Indicators are coupled at 150 mm/min. The test is stopped when the indicator is coupled or fails (breaks). Insertion force is recorded and plotted.

- For ear tags recommended for approval for bison, bovine, porcine, red deer and elk

The maximum insertion force, when using the manufacturer-designated applicator must not exceed 445 N. For approval, 90% or more of the indicators tested at each temperature must meet this requirement. Up to 10% of indicators tested at each temperature may exceed the 445 N limit by no more than 20 N.

At the above-mentioned conditions, there should be no breakage of the ear tags with the application of a force lower than 280 N.

- For ear tags recommended for approval for caprine, ovine and white-tailed deer

The maximum insertion force, when using the manufacturer-designated applicator must not exceed 225 N. For approval, 90% or more of the indicators tested at each temperature must meet this requirement. Up to 10% of indicators tested at each temperature may exceed the 225 N limit by no more than 10N.

At the above-mentioned conditions, there should be no breakage of the ear tags with the application of a force lower than 200 N.

E2. Former section merged with section E1

E3. Repealed section

E4. Tensile strength (de-coupling force)

Tensile strength is a measure of the ability of a material to withstand a longitudinal stress, expressed as the greatest stress that the material can stand without de-coupling.

Ten (10) indicators are used at each temperature range for this test. Test occurs at the following temperatures and relative humidity:

-35°C ± 2°C	50% rH ± 5%
+20°C ± 2°C	50% rH ± 5%
+40°C ± 2°C	50% rH ± 5%

Indicators will be stabilized at the test temperature and relative humidity for two hours prior to the test.

Using a test jig, the coupled indicators from the insertion force test (see section E1) are inserted into a slotted plate to allow them to be de-coupled when axial force is applied to the male portion. The de-coupling is used to describe the action/motion of the equipment i.e. positioned to pull the male and female tags apart. Indicators are de-coupled at 500mm/min. The test is stopped when the indicator is de-coupled. Axial force is recorded and plotted.

For approval, all of the indicators tested at each temperature must have a tensile strength between the below-mentioned value and 15% above:

- 280 N[3] for ear tags recommended for approval for bison, bovine and cervid;
- 200 N for ear tags recommended for approval for caprine and ovine (standard from BSI PAS66:2014);
- 180 N for ear tags recommended for approval for pigs.

[3] See ICAR standard "10.8.5.2.2.1.5.2 Ear tags not classified as flag tags"; URL: http://www.icar.org/wp-content/uploads/2016/03/Guidelines-Edition-2016.pdf

E5. Tamper Evidence Test

Indicators used in the Tensile strength test are evaluated for Tamper Evidence. All de-coupled indicators must be rendered unusable once decoupled. In two piece tags, the male portion must remain inside the female boss area to prevent re-application of the indicator. For either one piece or two piece indicators, the tag must not be able to be re-applied to an animal. For approval, 100% of de-coupled indicators must meet these criteria.

Annex F. Performance Test Requirements

HDX technology

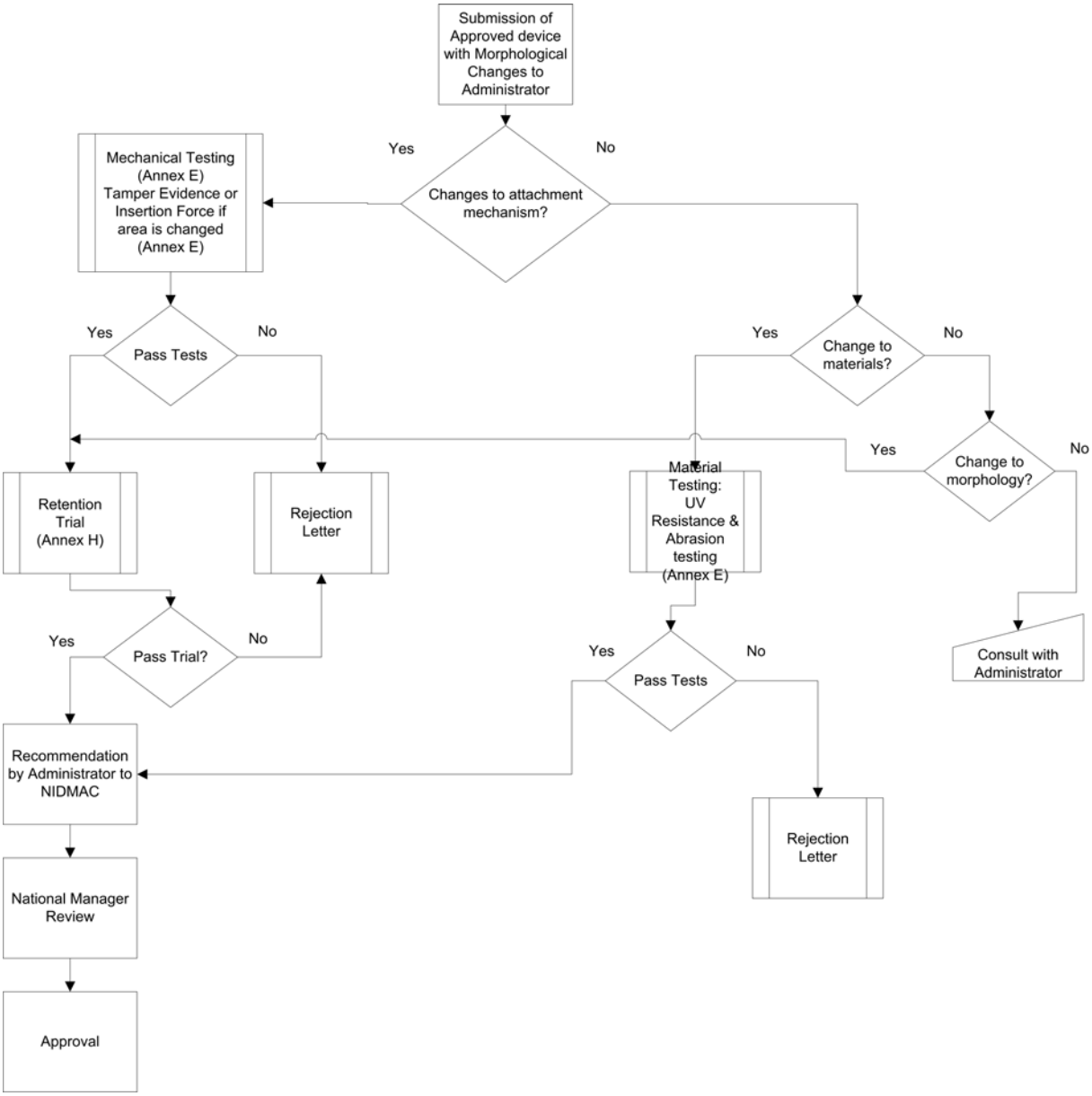
Electronic ear-tags applying HDX technology, shall be activated by a magnetic field strength of no more than 1.2 A/m, measured according to ISO standard 24631-3, section 7.6.5, "Minimal activating magnetic field strength in HDX mode", and shall develop a modulation amplitude equal to 10 mV, measured according to ISO standard 24631-3, section 7.6.7, "Modulation amplitude in HDX mode", by a magnetic field strength of no more than 1.2 A/m.

FDX technology

Electronic ear tags which uses FDX-B technology, shall be activated by a magnetic field strength of no more than 1.2 A/m, measured according to ISO standard 24631-3, section 7.6.4, "Minimal activating magnetic field strength in FDX-B mode", and shall develop a modulation amplitude equal to 10 mV, measured according to ISO standard 24631-3, section 7.6.6, "Modulation amplitude in FDX-B mode", by a magnetic field strength of no more than 1.2 A/m.

Annex G. Test requirements for morphological changes made to approved indicators

Figure 2. Test requirements for morphological changes made to approved indicators (RDIMS #10295501)



Annex H. Field trial guidelines and requirements

General description

H1. A **short-term field trial** is required in the approval process for approved indicators which undergone modifications such as weight, attachment mechanism, male stud, dimension or morphology (see Figure 3). The duration of the short-term field trial is 90 days from the day all the indicators being tested are applied to the animals.

H2. A **standard field trial** is required in the approval process for all non-approved indicators (see Figure 3). The duration of the standard field trial from the day all the indicators being tested are applied to the animals will be, at a minimum, twelve (12) months for bovine, bison, cervid and equid; and six (6) months for ovine, pigs, and caprine. The responsible administrator will confirm the duration of the field trial with the proponent but will not exceed 24 months.

H3. Unless otherwise specified, information under this annex applies to both short-term and standard field trials.

H4. The results of the field trial will be compared against the performance standards identified under section 5 of the Framework.

H5. The experimental design of all field trials will meet the performance objective identified under section 5.5 of the Framework.

Parameters

H6. At a minimum, the following parameters will need to be measured during the course of a field trial:

a) Number of indicators that did not read properly (pertinent to RFID indicators);
b) Number of indicators for which the identification number printed does not match the number scanned (pertinent to RFID indicators);
c) Number of indicators for which identification numbers were not legible;
d) Number of indicators for which material deteriorated;
e) Number of indicators that did not apply properly;
f) Number of indicators that did not remain affixed to the animal.

H7. The total number of issues observed with the tested indicator will be measured against the performance standards stated in the Framework.

H8. Forms recording issues observed with the indicators must be submitted to the NIDMAC when the trial results are submitted.

Selection of sites, environment

H9. Field trials must be run in Canada.

H10. Representative animal husbandry practices and supply chain environments should be selected.

H11. Field trials must be practical so that livestock managers can integrate them into normal husbandry and herd management operations. This will also encourage managers to retain enough animals bearing the indicators in their herds for the duration of the trial.

H12. The animals bearing the proposed indicator can be easily identified and segregated for the purpose of the study, and the date of indicator application can be established for each animal.

H13. It should be possible to gather and accurately record the information required, as all the indicators need to be accounted for on each occasion indicator performance is assessed.

H14. It should be possible to routinely account for all the identified animals.

Selection of animals

H15. The indicators being tested will be applied on animals belonging to the species for which approval is sought.

H16. To assist in ensuring that adequate animals are available at the end of the trial period, it is recommended that a substantial, representative herd be used.

H17. Most of the animals should be available on the property for the duration of the field trial.

H18. Animals should be in good health at the beginning of the trial.

Application of indicators

H19. The indicators must be applied to the animals with the manufacturer's recommended applicator and in accordance with the manufacturer's instructions.

H20. A representative of the manufacturer may witness all indicator applications and provide instructions prior to application.

H21. The animals must be easily identified (e.g. application of a secondary indicator) to allow the trial supervisor to establish with certainty those animals in the trial that have lost the indicators.

Preparation for field trials

H22. Preparation for trials may start once the indicator trial proposal has been approved.

H23. The manufacturer will provide to the organization conducting the trials:

a) the indicators of the type to be included in the trial
b) applicators as required
c) a copy of the device specifications and application instructions.

H24. The manufacturer will allocate a range of identification numbers for the purpose of the trial. The indicator will bear a manufacturer's code number instead of the country code. The words "Test Tag" will be printed on all devices on test.

H25. The indicators being trialed are not approved. Animals bearing a trial indicator are not exempted from identification regulatory requirements.

H26. Indicators which were tested should be removed from animals at the end of the trial.

Qualifications

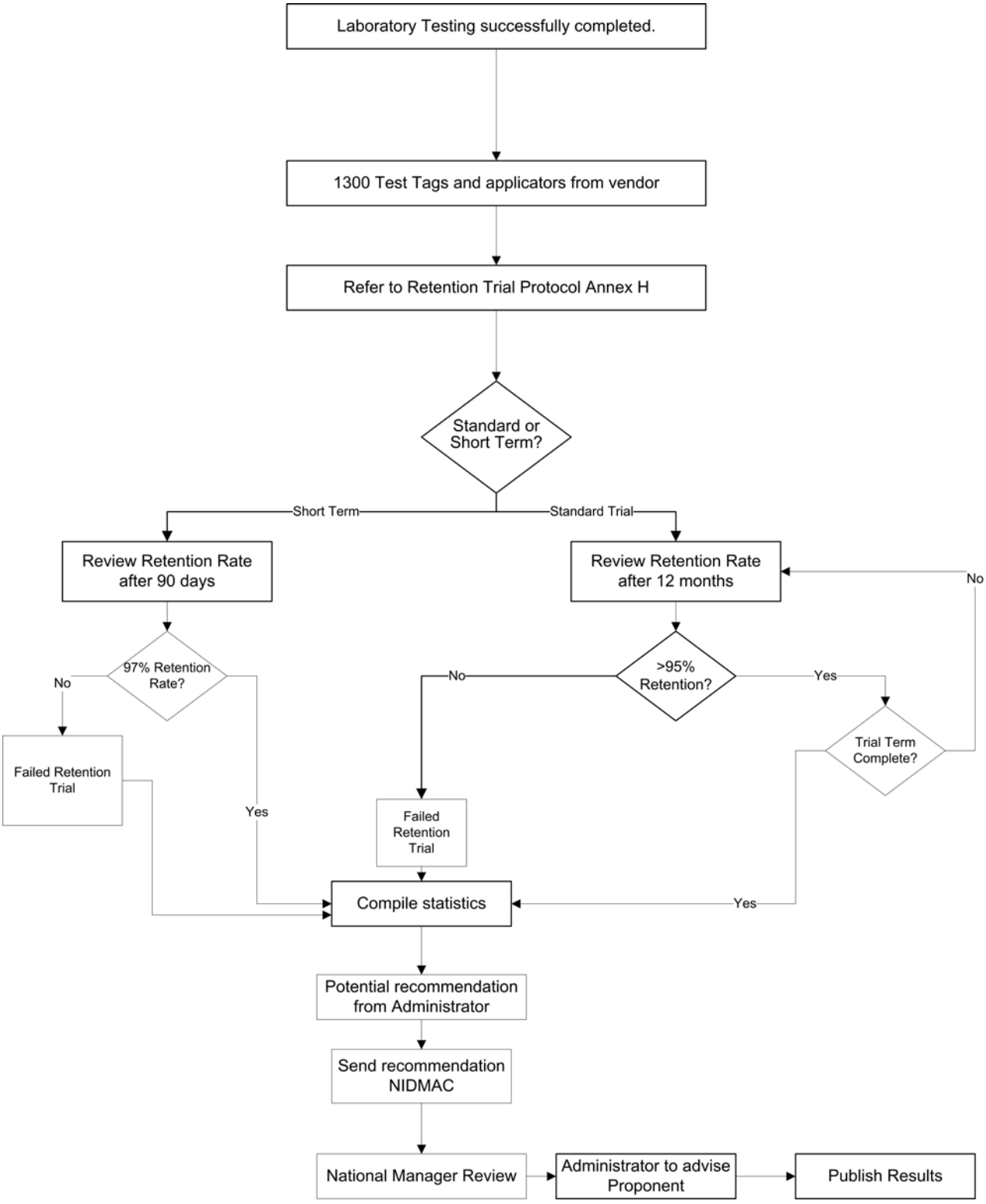
H27. The supervisor for the trial must demonstrate:

a) animal husbandry experience
b) statistics knowledge
c) a good knowledge about the indicators being tested
d) experience in conducting field experiments in the livestock sector

e) there is no conflict of interest (e.g. not drawing profits from the approval of the proposed indicator).

H28. In the event that the nominated trial supervisor is unable to continue with the supervision of the trial for any reason, the proponent should immediately notify the NIDMAC.

Figure 3. Indicator field trial process



Annex I. Evaluation protocol for indicators

Figure 4. Quality control evaluation process conducted at distribution centres for electronic indicators, (RDIMS #10295508)

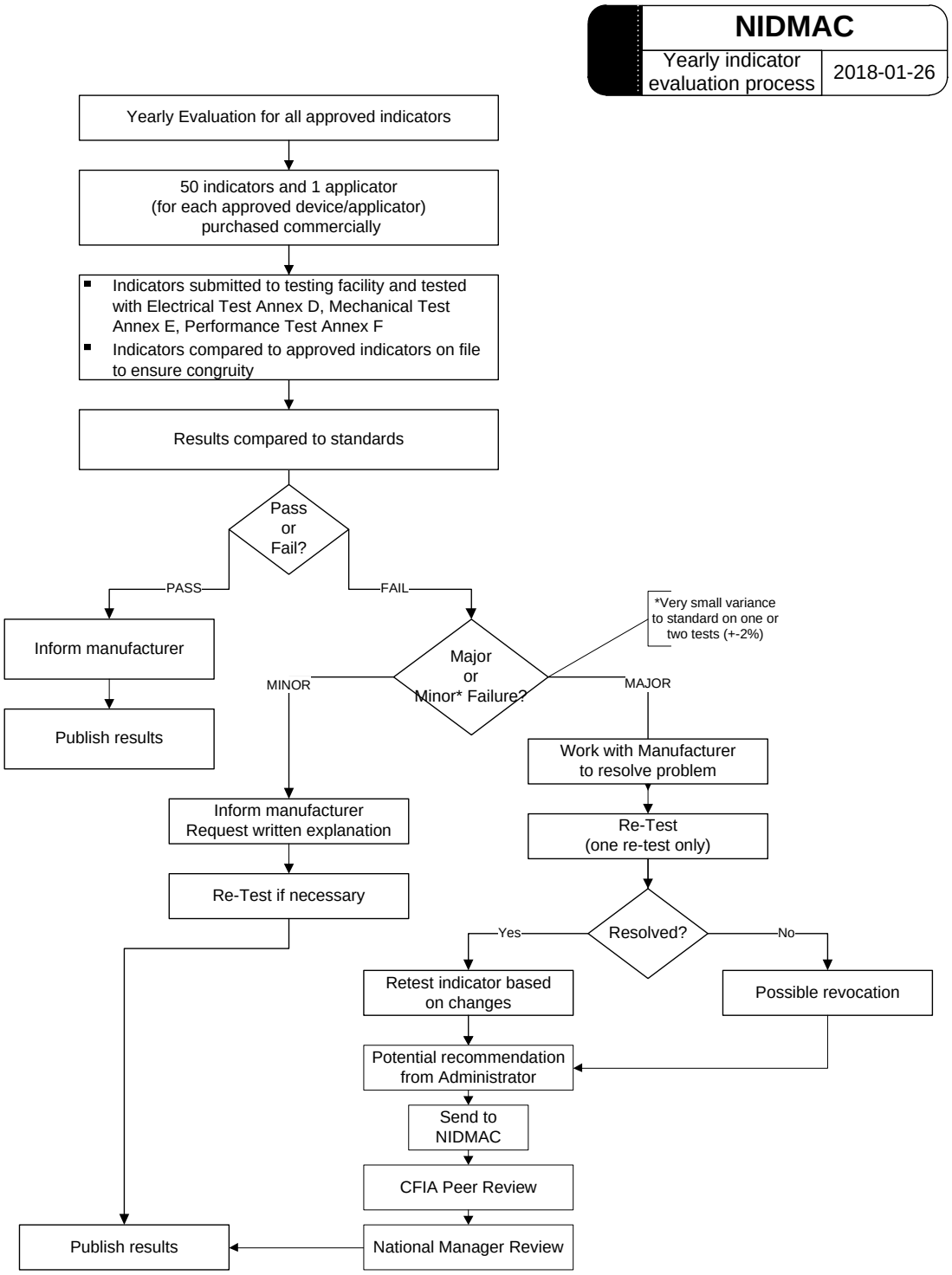


Figure 5. Post-processing electronic indicator evaluation process

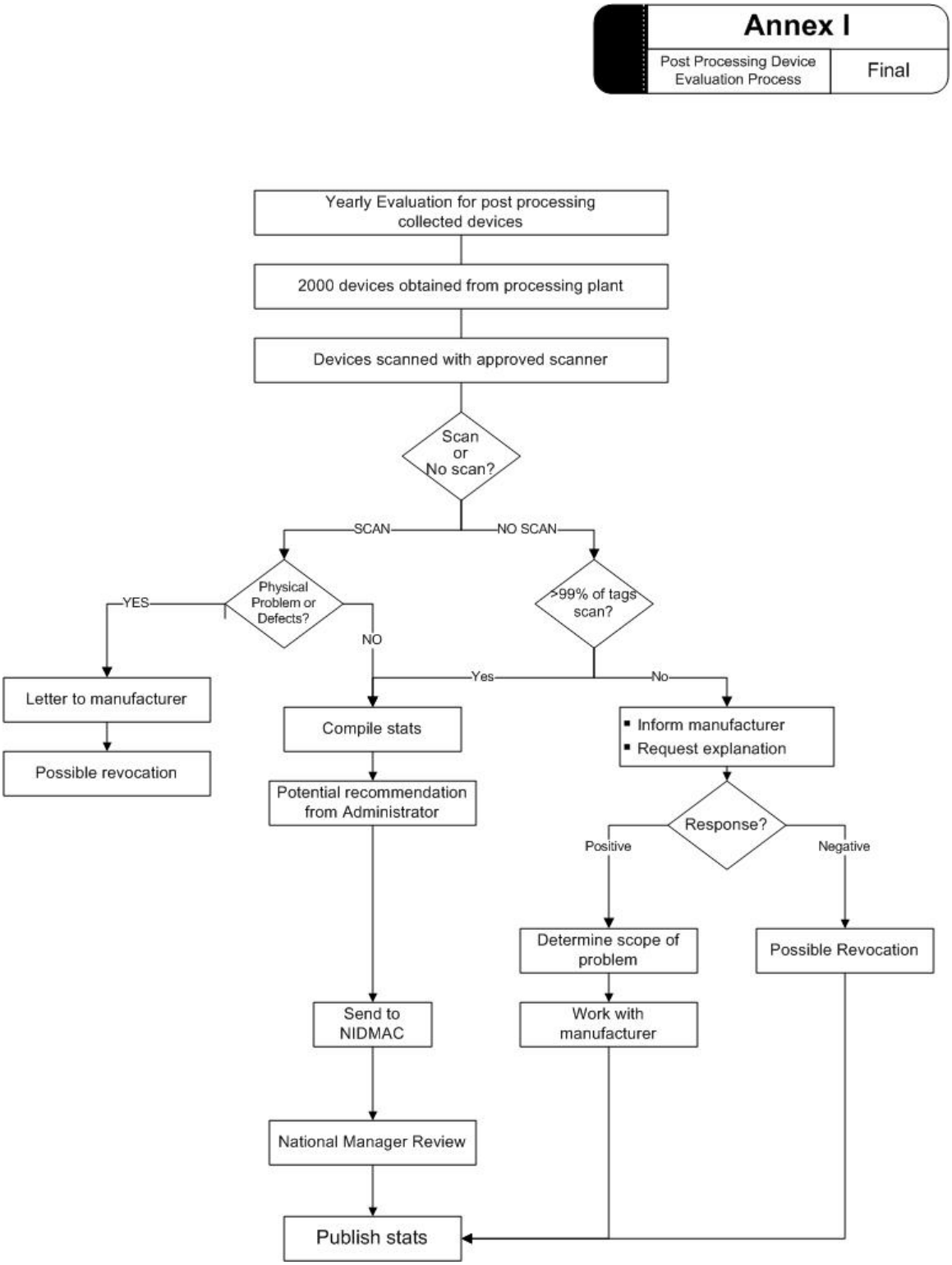
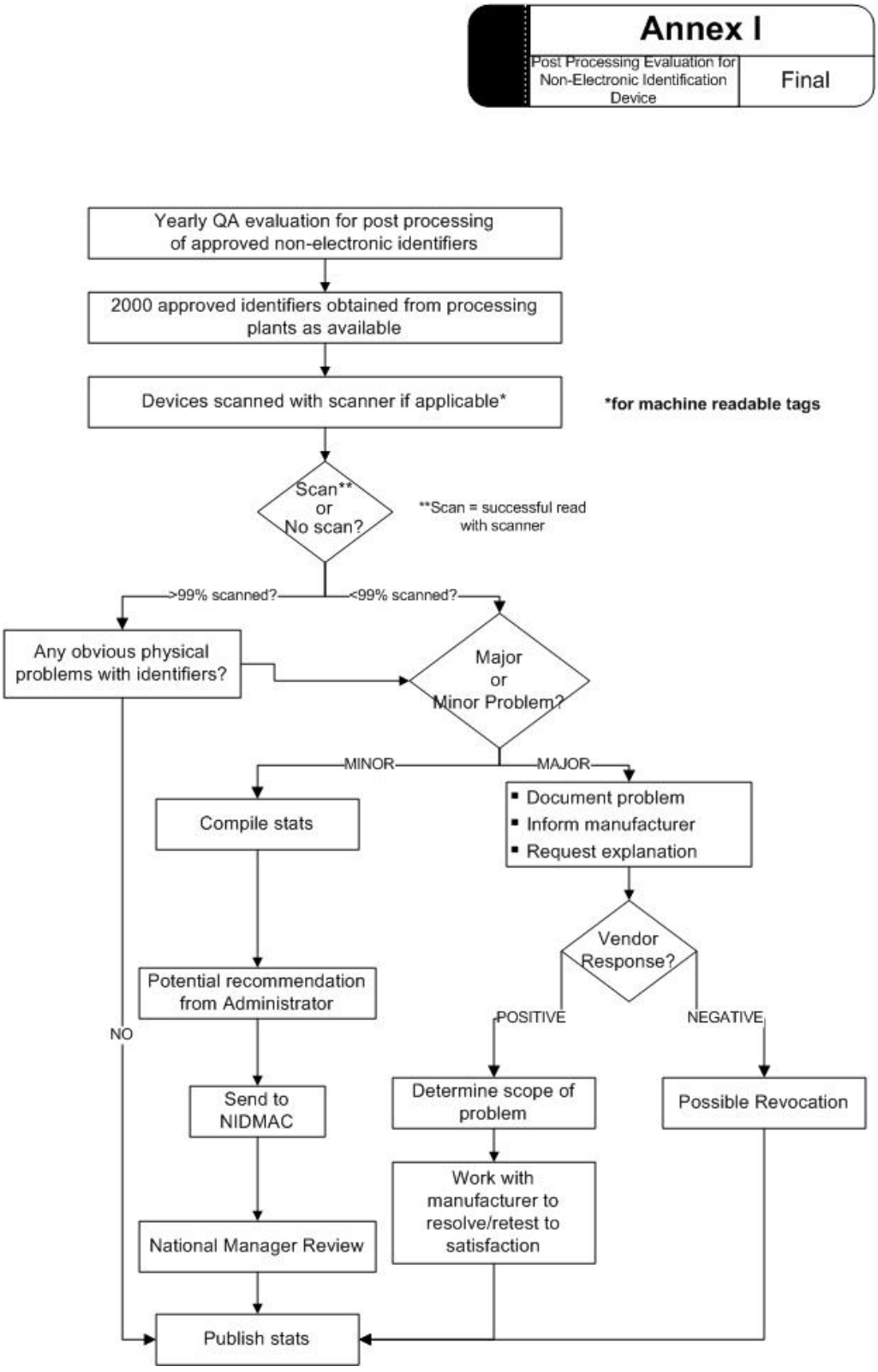


Figure 6. Post-processing evaluation for non-electronic indicator



Annex J. Indicator information to finalize approval

Manufacturers will provide the following information and documentation to the National Manager for an indicator to be approved by the Minister:

1. Official name of the indicator
2. Model number, SKU code, type of silicon and manufacturer of silicon used
3. Technology used (e.g. HDX indicator, FDX-B indicator, non-electronic indicator)
4. Weight of the indicator in grams
5. Colour photo (JPEG) images of the indicator (6 photos in total) with the following specifications:
   - 5.1. resolution: 300 PPI
   - 5.2. images of front (female) including the following:
     - 5.2.1. frontal image
     - 5.2.2. rear image
     - 5.2.3. profile/side image
   - 5.3. images of back (male panel or button) including the following:
     - 5.3.1. frontal image
     - 5.3.2. rear image
     - 5.3.3. profile/side image

   The identification number on the indicator being pictured will fall within the range for the animal species to which the indicator was approved.

6. Release of copyright (Annex K)
7. Indicator application guidelines
8. Information on the applicator

Annex K. Release of copyright

Release of Copyright

I, the undersigned, declare that the photograph(s) <<insert indicator>> is/are original, and that [insert name of author/owner] holds exclusive copyright in the photograph(s). I hereby grant Her Majesty the Queen, as represented by the Canadian Food Inspection Agency ("CFIA"), permission to reprint, publish or otherwise use this/these photograph(s) for any purpose relating to the administration and enforcement of the *Health of Animals Regulations,* C.R.C., c.296 ("HAR"), including use in any communication products, such as posting on the CFIA website for the purpose of advising that the featured indicator(s) has/have been approved by the Minister under section 173, HAR.

Name:_____
Telephone:_____
e-Mail: _____
Title: _____
Address: _____
_____
_____

Signature: _____ Date: _____