National Livestock
Identification System

NLIS Animal Identification Technology Approval Program Rules

Integrity Systems Company Limited (ISC)

Version 2.0

29 June 2023

CONTENTS

INTRODUCTION 1

1 SCOPE 3

2 PROGRAM ADMINISTRATION AND RESPONSIBILITIES 4

3 APPROVAL REQUIREMENTS AND SCOPE OF APPROVAL 12

4 EVALUATION PROCESS 14

5 SURVEILLANCE 27

6 APPEALS 28

7 APPROVAL AGREEMENT, USE OF NLIS LOGO AND LABEL CLAIMS 29

8 RENEWAL OF APPROVAL 32

9 PROGRAM DIRECTORY 33

10 CHANGES TO APPROVAL 34

11 RECALLS, SUSPENSION, WITHDRAWAL AND SANCTIONS 35

12 FEES AND CHARGES 40

13 COMPLAINTS AND MARKET FEEDBACK 41

14 CONFIDENTIALITY, COMMUNICATIONS AND NOTICES 44

15 PROGRAM OVERSIGHT AND REVIEW 46

16 GOVERNING LAW 47

17 DOCUMENT CONTROL 48

ANNEX A: Nonconformities 49

ANNEX B: Field Trial Protocols for Animal Identification Technologies 52

The series of documents which make up the *NLIS Animal Identification Technology Approval Program Approval Requirements* were prepared based upon consultation and collaboration with the NLIS Standards Working Group, the NLIS Standards Committee, Integrity Systems Company Ltd, Australian Government, state and territory government departments of primary industries and animal identification technology Suppliers.

These documents were formally adopted by SAFEMEAT on 29 June 2023.

INTRODUCTION

Animal identification technologies for use under NLIS are required to be **approved** under the *NLIS Animal Identification Technology Approval Program* (the 'Program') and become 'NLIS Approved Technologies'. Initial approval is based on a five-year cycle and reapproval for the same animal identification technology can be sought every five years thereafter.

Supply chain participants throughout Australia have a legal obligation to use NLIS Approved Technologies to register movement details on the NLIS database when identified animals move between properties. For this reason, supply chain participants that could potentially receive identified animals must have the capacity to reliably read the NLIS Approved Technologies and comply with their compliance requirements.

After six months of a field trial, animal identification technologies that meet the performance criteria may be considered for conditional approval which, subject to jurisdictional approval, allows for the commercial sale of the technology in Australia. Full approval may be considered after successful field trials or commercial sales performance.

Individual state and territory governments may impose other requirements and authorisation processes, such as regulations regarding the approval, use and supply of animal identification technologies within their jurisdiction, and have their own processes in place for managing livestock identification and traceability. Furthermore, industry policy bodies and SAFEMEAT may also make policy decisions in relation to NLIS that influence production and supply of animal identification technologies and the technology platforms that are permitted.

Animal identification technologies include any technology used to identify livestock. This could include, but is not limited to, all livestock tags, devices, identifiers, buttons, bands, transponders, microchips, all of which may contain electronic or non-electronic components, and machine-readable codes, such as bar or quick response (QR) codes.

An approved animal identification technology consists of:

- the physical components;
- the system or tool for application of the technology to the animal;
- instructions to be supplied to the user of the technology; and
- packaging, including statements and markings on the packaging.

The three primary documents which form the Approval Requirements are the:

a) *NLIS Animal Identification Technology Approval Program Fundamentals and Vocabulary*;

b) *NLIS Animal Identification Technology Approval Program Rules* (the 'Program Rules'; this document); and

c) *Requirements for NLIS Animal Identification Technology* (the 'Standard').

This document contains all the requirements for the **approval process** used by the Program Administrator and Standards Committee to assess animal identification technologies and grant, or otherwise, approval to supply animal identification technologies for use under NLIS. It specifies the approval process and sets out of the responsibilities of the parties associated with the Program (i.e. the Program Administrator, the Standards Committee and its secretariat, Suppliers, Field Trial Supervisors and Auditors). In addition, the Program Rules include the Approval Agreement between Suppliers of NLIS Approved Technologies and the Program Administrator, along with the NLIS Logo License.

This document forms part of the legally binding agreement that Suppliers enter into with the Program Administrator as part of the approval process.

In summary, the Program Rules cover the following elements:

a) responsibilities of the parties to the Program;

b) specification of the requirements that must be demonstrated by Applicants and Suppliers of NLIS Approved Animal Identification Technology;

c) application, reapplication and approval process, including decision making and appeals;

d) specifications for protocols to be observed during field trials;

e) ongoing surveillance activities required in order to maintain approval;

f) dealing with changes, suspension or withdrawal of approvals;

g) reference to fees and charges;

h) information management, including formal notices, confidentiality, public information and records; and

i) provision for the periodic review of the Program and the Approval Requirements.

1 SCOPE

The scope of the *NLIS Animal Identification Technology Approval Program* is the approval of any technology used to identify livestock, specifically cattle, sheep and goats, under NLIS.

The requirements in this document are referenced as part of the Approval Requirements. To obtain and maintain approval under the Program the Applicant or Supplier shall:

a) establish and maintain processes to demonstrate the ongoing fulfilment of the Approval Requirements;

b) apply for approval;

c) undergo the approval process in accordance with these Program Rules;

d) pay all necessary fees, charges and disbursements; and

e) undergo periodic surveillance activities after the initial approval to demonstrate the NLIS Approved Animal Identification Technology continues to fulfil the Approval Requirements.

2 PROGRAM ADMINISTRATION AND RESPONSIBILITIES

2.1 Program Administrator

The Program is administered by the Program Administrator.

2.2 Parties associated with the Program

Operation of the Program is undertaken through the involvement of the following parties:

a) the Program Owner

b) the Program Administrator;

c) the Standards Committee;

d) Applicants and Suppliers of NLIS Approved Technologies;

e) Field Trial Supervisors;

f) Field Trial Participants; and

g) Approved Auditors.

These Program Rules form part of the legally enforceable agreements which can exist between the above parties.

2.3 Responsibilities of the Parties

All parties operating under the Program shall work together consultatively and collaboratively for the benefit of the Program and NLIS in general.

2.3.1 Program Owner

The responsibilities of the Program Owner include ensuring that:

a) the Program is maintained and satisfies the primary purpose;

b) the Approval Requirements are up-to-date; and

c) all parties are equally informed about changes and interpretations of the Approval Requirements.

2.3.2 Program Administrator

The responsibilities of the Program Administrator include:

a) developing and reviewing these Program Rules and recommending their approval to the Program Owner;

b) in conjunction with the Standards Committee, maintaining oversight and periodically reviewing and recommending changes to Approval Requirements;

c) notifying any changes regarding the Approval Requirements to the parties involved and setting any transition deadlines or other arrangements;

d) identifying and managing risks associated with administration of the Program Rules, including the integrity of the NLIS, risks to impartiality and reputation of the livestock industry;

e) maintaining finances, reserves and insurances to ensure ongoing operation of the Program and to cover any liabilities arising from its administration;

f) setting fees and charges associated with the Program, and invoicing and receipting all relevant fees and charges associated with Applicants and Suppliers;

g) approving, appointing and monitoring the performance of Field Trial Supervisors, Field Trial Participants and Approved Auditors;

h) administering and operating the Program in accordance with the Program Rules in an impartial and objective manner, using a documented management system;

i) managing data, information and confidentiality requirements;

j) providing a secure document management and exchange platform, and any supporting information technology infrastructure and databases (including the Program Directory) for use by the Program Administrator, Field Trial Supervisors, Field Trial Participants, Approved Auditors and Applicants or Suppliers;

k) maintaining terms of reference and supporting any committees necessary for the administration of the Program, including the Standards Committee;

l) managing direct communication and receiving applications from Applicants for approval, checking and evaluating the applications, and allocating full and accepted applications to Field Trial Supervisors, Field Trial Participants and Approved Auditors for evaluation;

a) coordinating and overseeing Field Trials, including assigning a Field Trial Property, Field Trial Participant and Field Trial Supervisor to an Applicant;

b) issuing and managing Approval Agreements based on consideration of recommendations from the Standards Committee and confirmation upon request of the current approval status;

c) coordinating and monitoring ongoing conformity with the Approval Requirements through surveillance activities;

d) receiving and actioning complaints using its complaints handling procedure and dispute resolution;

e) providing communications, monitoring performance, reporting and periodic review of the impacts and outcomes of the Program; and

f) dealing with any correspondence, media enquires or other communications about the Program, including any instances of incorrect, inappropriate or misleading references to approval.

2.4 The Standards Committee

The responsibilities of the Standards Committee include:

a) reviewing and maintaining the Standard and recommending the approval of the Standard to the Program Owner;

b) reviewing applications for approval of animal identification technologies, assessing such applications against the Approval Requirements (including trials) and making recommendations relating to the approval, or not, of animal identification technologies to the Program Administrator;

c) assessing Field Trial Supervisors, Field Trial Managers and Auditors and making recommendations to the Program Administrator in relation to the approval of such;

d) providing clarification or interpretation as to the intent of the Approval Requirements in order to achieve the practical operation of the Program. In making such clarification or interpretation, the Standards Committee shall ensure the objective of the Approval Requirements is achieved; and

e) in conjunction with the Program Administrator, monitoring ongoing conformity of NLIS Approved Technologies and, where necessary:

   i. making recommendations relating to the suspension or withdrawal of approval to the Program Administrator; and

   ii. making determinations relating to the amendments of the Approval Requirements in order to improve conformity.

2.5 Applicant and Suppliers

The responsibilities of the Applicant or Supplier include:

a) being a legal entity in Australia;

b) ensuring the following originates in Australia:

   i. encoding, printing and packaging of the animal identification technology; and

   ii. receiving, fulfilling, verifying and dispatching orders;

c) reviewing, understanding and investing in systems and training to demonstrate ongoing conformity with the Approval Requirements;

d) making applications for animal identification technologies to be approved under the Program and signing the Approval Agreement including the NLIS Logo License;

e) undertaking actions and providing access to information to enable evaluations and approval activities to be undertaken, including the effective and timely closure of any nonconformities;

f) adhering to the terms and conditions of the Approval Agreement and only referring to approvals in accordance with the Program Rules;

g) notifying the Program Administrator of any circumstances that may affect the Applicant or Supplier's ability to fulfil the Approval Requirements;

h) paying all relevant fees, charges and royalties that the Program Administrator may establish and revise from time-to-time; and

i) managing information, confidentiality requirements, document exchanges, databases, reporting and communications, and providing notices in relation to the Program Rules.

2.6 Field Trial Supervisors

The responsibilities of the Field Trial Supervisor include:

a) demonstrating and maintaining appropriate levels of competency, including:

   i. an understanding of:

      1) standard operating procedures for identifying animals and recording animal movements on the NLIS database;

      2) typical animal husbandry practices; and

      3) assessment methodologies; and

ii. general abilities in:

1) communicating effectively to persons at any level using appropriate and relevant language(s), terms, expressions and speech. All Field Trial Supervisors must be able to read, write and converse in the English language;

2) reading and writing with sufficient speed, accuracy and comprehension to record, take notes and effectively and accurately communicate audit findings and conclusions; and

3) interviewing to obtain relevant information by asking open-ended, well formulated questions and listening to understand and evaluate the answers; and

b) avoiding any perceived or real conflict of interest. This includes ensuring there has been no relationship with any Applicant or Supplier within the previous 24 months (e.g. as a business associate, supplier, purchaser, relative, acquaintance, friend, partner, employee, volunteer, intern, contractor, researcher, advisor or consultant) that would give rise to a conflict of interest.

NOTE Acting as a Field Trial Supervisor for different Applicants or Suppliers would generally not give rise to a conflict of interest.

c) obtaining Program Administrator approval to effectively supervise field trials;

d) undertaking field trial supervision activities as directed by the Program Administrator and in accordance with Annex B, in an impartial, objective and timely manner;

e) managing information, confidentiality requirements, document exchanges, databases, reporting and communications in relation to the Program;

f) reading and understanding their duties and acknowledging their preparedness to perform these duties by signing the Field Trial Supervisor Declaration Form; and

g) where the Field Trial Supervisor has been appointed to a field trial and is unable to attend a scheduled assessment or continue with the supervision of the trial for any reason (e.g. change of employment, retirement, ill health etc.), advising the Program Administrator within seven days of becoming aware of the reason.

2.7 Field Trial Participants

The responsibilities of the Field Trial Participants include:

a) demonstrating and maintaining appropriate levels of competency, including an understanding of:

   i. standard operating procedures for identifying animals and recording animal movements on the NLIS database; and

   ii. typical animal husbandry practices;

b) undertaking usual on-farm procedures including maintaining on-farm records consistent with compliance requirements;

c) adhering to relevant compliance requirements;

d) avoiding any perceived or real conflict of interest. This includes ensuring there has been no relationship with the Applicant or Supplier within the previous 24 months (e.g. as a business associate, supplier, purchaser, relative, acquaintance, friend, partner, employee, volunteer, intern, contractor, researcher, advisor or consultant) that would give rise to a conflict of interest;

   NOTE Acting as a Field Trial Participant for different Applicants or Suppliers would generally not give rise to a conflict of interest.

e) undertaking field trial activities as directed by the Program Administrator and in accordance with Annex B, in an impartial, objective and timely manner;

f) managing information, confidentiality requirements, document exchanges, databases, reporting and communications in relation to the Program;

g) reading and understanding their duties and acknowledging their preparedness to perform these duties by signing the Field Trial Participant Declaration Form; and

h) maintaining field trial records as specified by the Program Administrator and submitting such to the Program Administrator within the specified timeframe.

2.8 Approved Auditors

The responsibilities of the Approved Auditors include:

a) demonstrating and maintaining appropriate levels of competency, including:

   i. knowledge of:

1) generic audit principles, practices and techniques, as specified in ISO 19011 and the Approval Requirements sufficient to conduct audit and evaluation activities, including the verification of the effective management and control of processes, management reviews, internal audits, and corrective and preventive actions by Applicants and Suppliers;

2) the Approval Requirements sufficient to determine if they have been effectively implemented and are being conformed with;

3) the terminology, practices, processes and regulations common to animal identification sufficient to understand the expectations in the context of the Approval Requirements; and

4) the types of operations of an Applicant or Supplier sufficient to understand how such an organisation can operate, and how the organisation can apply the Approval Requirements;

ii. general abilities in:

1) communicating effectively to persons at any level using appropriate and relevant language(s), terms, expressions and speech. All Approved Auditors must be able to read, write and converse in the English language;

2) reading and writing with sufficient speed, accuracy and comprehension to record, take notes and effectively and accurately communicate audit findings and conclusions;

3) interviewing to obtain relevant information by asking open-ended, well formulated questions and listening to understand and evaluate the answers; and

4) conducting and managing an audit to achieve the audit objectives within the agreed timeframe;

b) obtaining Program Administrator approval to effectively perform the evaluation of production processes of animal identification technology;

c) undertaking evaluation and approval activities as directed by the Program Administrator and in accordance with the Approval Requirements, in an impartial, objective and timely manner;

d) avoiding any perceived or real conflict of interest. This includes ensuring there has been no relationship with the Applicant or Supplier within the previous 24 months (e.g. as a business associate, supplier, purchaser, relative, acquaintance, friend, partner, employee, volunteer, intern, contractor, researcher, advisor or consultant) that would give rise to a conflict of interest;

e) managing information, confidentiality requirements, document exchanges, databases, reporting and communications in relation to the Program;

f) reading and understanding their duties and acknowledging their preparedness to perform these duties by signing the Approved Auditor Declaration Form; and

g) where the Approved Auditor has been appointed to an Applicant or Supplier and is unable to attend a scheduled assessment for any reason (e.g. change of employment, retirement, ill health etc.), advising the Program Administrator within seven days of becoming aware of the reason.

3 APPROVAL REQUIREMENTS AND SCOPE OF APPROVAL

3.1 Approval Requirements

The Approval Requirements under the Program include:

a) the *NLIS Animal Identification Technology Approval Program Rules* (the 'Rules' - this document);

b) the *Requirements for NLIS Animal Identification Technology* (the 'Standard');

c) any requirements included in field trial plans (where relevant);

d) the Approval Agreement including the NLIS Logo License (where relevant); and

e) all instructions and communications made from time-to-time by the Program Administrator on the administration and operation of the Program, including any:

   i. formal interpretations of Approval Requirements;

   ii. payment of all applicable fees, charges and disbursements that may be established and revised from time-to-time; and

   iii. policies, procedures, instructions, forms and other documents that are necessary for the administration and operation of the Program.

3.2 Scope of Approval

Upon demonstrated fulfilment of the Approval Requirements and a decision to grant approval, the scope of approval covers:

a) the complete animal identification technology:

   i. including all physical components and supplementary items such as the application system or tool, instructions and packaging;

   ii. without any subsequent substitution or change to any components or the manufacturing process; and

   iii. with options for use as breeder and post-breeder technology;

b) the type of technology the animal identification technology has been approved for use as;

NOTE Electronic animal identification technologies incorporating low frequency RFID are not eligible for approval as another type of technology.

c) the species which the animal identification technology is approved for use with;

d) the product field code allocated to that NLIS Approved Technology;

e) how the NLIS Approved Technology is applied to an animal;

f) all Australian-based sites of the Supplier where the NLIS Approved Technology is produced;

g) the Approval Requirements;

h) the validity period of approval; and

i) any conditions or variations to the Approval Requirements sanctioned by the Program Administrator.

Complete animal identification technologies consist of a whole primary component or separate multiple components, one of which is considered the primary component, that when applied to the animal become a whole component. Only the complete animal identification technology is approved. Substitution or change to whole or multiple components is not permissible after approval.

Components from one NLIS Approved Technology cannot be interchanged with other NLIS Approved Technologies or other components of NLIS Approved Technologies.

If substitution or change is desirable this constitutes a change to the NLIS Approved Technology, and the Supplier must first inform the Program Administrator for their further consideration.

Approval of animal identification technologies under this Program is only for the features necessary to facilitate the primary purpose. The Program Owner, Program Administrator, Standards Committee, Approved Auditors and Field Trial Supervisors are not responsible for the assessment or performance of any features which do not directly support the primary purpose.

4 EVALUATION PROCESS

4.1 Evaluation process overview

The evaluation process consists of the following steps:

a) concept consideration;

b) prerequisites (e.g. ICAR certification);

c) application;

d) application review;

e) assignment of evaluation personnel;

f) audits;

g) nonconformities;

h) audit evaluation reports;

i) field trials and testing; and

j) approval decisions:

   i. experimental approval;

   ii. conditional approval; and

   iii. full approval.

4.2 Concept consideration

The Program Administrator supports innovation and encourages organisations to develop animal identification technologies which may enhance NLIS. Retention and fulfilment of the primary purpose remain the key principles for any animal identification technology. The following are considered priorities when considering new or alternative technologies for use under NLIS:

a) the animal identification technology shall:

   i. achieve the primary purpose throughout the supply chain; and

   ii. ensure the technology is designed such that when applied the technology can remain applied to the animal for its lifetime.

The Program Administrator shall facilitate the consideration by the Standards Committee and provide feedback on concepts for new and alternative animal identification technologies.

The proponent of the new or alternative animal identification technologies shall:

a) prior to submitting their animal identification technology concept for feedback, familiarise themselves fully with:

   i. the Program and Approval Requirements;

   ii. all compliance requirements associated with NLIS; and

   iii. industry and jurisdictional policy positions;

b) submit their animal identification technology concept to the Program Administrator and describe:

   i. the animal identification technology concept, including its physical components, application methods and proposed user instructions and packaging;

      NOTE Concept samples may be submitted during this stage.

   ii. how the animal identification technology concept will fulfil and maintain:

      1) the Approval Requirements;

      2) compliance requirements associated with NLIS; and

      3) industry and jurisdictional policy positions;

   iii. any anticipated conflicts or deviations with ii 1), 2) and 3) and how these will be addressed;

   iv. identify any aspects of the animal identification technology which are patent protected;

   v. any research which demonstrates the animal identification technology's capability to fulfil:

      1) the primary purpose and support the NLIS objectives;

      2) compliance requirements;

      3) industry and jurisdictional policy positions;

vi. how the animal identification technology will integrate or operate concurrently with existing animal identification infrastructure used throughout the supply chain (for example, existing technologies that are used on properties, at sale yards, at processing establishments and at export facilities etc.); and

vii. any applicable ISO or equivalent standards and associated testing or assessment methods, as well as production quality controls that are necessary to enable the evaluation of the animal identification technology and demonstration of consistent fulfilment of Approval Requirements.

In addition, where the concept is proposing an alternative animal identification technology, the proponent shall also include in their concept submission:

a) any outcomes of industry and jurisdictional consultation, feedback and views;

b) a detailed and independently prepared incremental cost-benefit analysis, taking into account the cost of ensuring the supply chain has the capacity to use the animal identification technology under NLIS, which demonstrates a net commercial benefit to the industry

NOTE Capacity may relate to human capital and capability, infrastructure and software etc.

c) the methodology for introduction of the new technology through the supply chain;

d) how the animal identification technology will be able to be utilised for the primary purpose at sites with existing NLIS infrastructure throughout the supply chain (for example, on properties, at sale yards, at processing establishments and at export facilities etc), including:

i. details on infrastructure required at those sites that is commercially available and fit for the intended purpose, including the names of companies that can supply and support the infrastructure;

ii. documented performance of such infrastructure within typical supply chain locations including but not limited to properties, sale yards, processing establishments and export facilities etc; and

NOTE Data relating to performance may be from overseas but must be applicable to Australian supply chain scenarios.

iii. evidence of human and animal safety of the alternative technology and infrastructure suitable for supply chain use;

e) how compatibility with the NLIS database and industry data management protocols will be achieved; and

NOTE Industry data management protocols may relate to software, software integration etc.

f) a risk assessment which impartially determines:

i. impact on current NLIS technology (i.e. compatibility, numbering format, infrastructure); and

ii. contingency plans for technology failure, recalls and replacements or any other risks associated with the technology failing to achieve the primary purpose or compromising NLIS and Australia's market access.

NOTE Such a risk assessment should be undertaken on the basis of ISO 31000.

The Program Administrator shall review the submission with the assistance of the Standards Committee and in consultation with industry, the jurisdictions and relevant experts as necessary, and provide feedback to the Supplier on their animal identification technology concept.

NOTE Applicants should expect that the information provided may be circulated by the Program Administrator to industry and the jurisdictions for review and feedback. Therefore, any commercial in confidence information should be identified as part of the application process.

The Program Administrator in consultation with the Standards Committee may propose an alternative approval process, including testing and field trial parameters.

4.3 Prerequisites

For any animal identification technology that uses low frequency RFID, the Applicant or Supplier shall obtain ICAR certification for that technology prior to applying for experimental approval and reapproval under the Program.

4.4 Application

Under the Program there are three types of applications:

a) application for experimental approval which shall be made by Applicants seeking to undertake field trials or similar assessments as part of the process to gain conditional approval;

b) application for conditional approval which shall be made by Applicants who, where necessary, have completed six-months of their field trial as part of the process to gain full approval; and

c) application for full approval for:

i. Applicants who have completed any required field trials; and

ii. Suppliers who have been supplying conditionally approved technology for at least six months and have demonstrated consistent fulfilment of the Approval Requirements; or

iii. Suppliers who are seeking to renew their full approval.

Any legal entity may make an application for one of the above if it:

a) fulfils the responsibilities for Applicants and Suppliers under these Program Rules;

b) has read and understood the Approval Requirements;

c) has developed and implemented processes that enables it to demonstrate the ongoing fulfilment of Approval Requirements;

d) has completed and signed the Application Form, which includes the Approval Agreement and Declaration; and

e) submits with the Application Form samples of the complete animal identification technology, as specified in Table 1 and all supplementary items.

Table 1: Number complete animal identification technology samples to be submitted with the Application Form

Status being applied for	Technology type	Number of complete units to be submitted based on 80:20 of breeder and post-breeder
Experimental approval	Electronic - RFID	80 units
	Non-electronic - Physical identification	30 units
Full approval Including reapproval	All	30 units

Animal identification technology samples submitted shall not be returned and shall be retained by the Program Administrator and used in initial testing or as reference units for ongoing testing and comparison.

4.5 Application review

The Program Administrator shall undertake a review of each application to ensure it has been correctly completed in full, including submission of all necessary samples and supporting information. Where information is not clear or missing, the Program Administrator shall request further information from the Applicant or Supplier.

The Program Administrator shall submit the application and any associated information to the Standards Committee for their consideration. Based on the outcome of the Standards Committee's consideration, the Program Administrator shall:

a) if required, request further information from the Applicant or Supplier to support informed consideration of their application; and

b) provide any relevant feedback on the application from the Standards Committee to the Applicant or Supplier.

When the Program Administrator and the Standards Committee are satisfied with the application, the Program Administrator shall accept the application and inform the Applicant of such.

4.6 Assignment of evaluation personnel

Once the Program Administrator has accepted the application it shall assign an Approved Auditor and, where relevant, a Field Trial Property, Field Trial Participant and Field Trial Supervisor. The Approved Auditor, and where required Field Trial Supervisor, will then make arrangements with the Applicant or Supplier for audits and any required field trial assessments.

The Approved Auditor, and where required the Field Trial Supervisor and Field Trial Participant, must not have had a relationship with the Applicant or Supplier within the previous 24 months (e.g. as a business associate, supplier, purchaser, relative, acquaintance, friend, partner, employee, volunteer, intern, contractor, researcher, advisor or consultant) that would give rise to a conflict of interest.

NOTE Acting as an Approved Auditor, Field Trial Supervisor or Field Trial Participant for the Applicant or Supplier previously would generally not give rise to a conflict of interest.

4.7 Audits

Evaluation activities shall include a site audit conducted by an Approved Auditor of the sites(s) of the Applicant or Supplier to observe the demonstrated fulfilment of the Approval Requirements. Site visits will often include, but are not limited to:

a) a walk through the site and observation of production processes;

b) observation of animal identification technologies;

c) inspection of site infrastructure and physical resources;

d) interviews and verbal exchanges with personnel; and

e) review of site resources and records.

Audits shall be undertaken by Approved Auditors:

a) prior to granting:

   i. experimental approval;

ii. conditional approval; and

iii. full approval; and

b) on a periodic basis after full approval has been granted, as prescribed by the Program Administrator for the duration of the full approval period specified in the Approval Agreement.

The scope of an audit may vary based upon the approval status being sought.

The Program Administrator may also undertake additional or unannounced audits in response to any concerns that the NLIS Approved Technology is not fulfilling Approval Requirements on an ongoing basis.

The Program Administrator shall prescribe the content of audits, including the following:

a) fulfilment of Approval Requirements;

b) follow up on any nonconformities and corrective actions undertaken in response to past audits, audits from other auditing activities, or government agencies;

c) follow up on any complaints associated with the NLIS Approved Technology;

d) where relevant, reconciliation of unique identifications of NLIS Approved Technologies with the NLIS database;

The Program Administrator may accept a current ISO 9001 certificate covering the manufacture, fabrication and supply of the animal identification technology if the certificate:

a) covers the complete animal identification technology (including all components, such as transponders and applicators) and, where relevant, the recording and registering on the NLIS database of unique numbering for each individual animal identification technology unit;

b) specifically refers to conformity with the Approval Requirements;

c) is issued to a site within Australia; and

d) is issued by an accredited ISO 9001 certification body that is accredited by a signatory of the International Accreditation Forum (IAF) Multilateral Agreement (MLA) for quality management system certification.

NOTE The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) is an IAF member and signatory of the IAF MLA for quality management system certification accreditation.

The Approved Auditor shall raise nonconformities in accordance with section 4.8 where fulfilment of Approval Requirements has not been demonstrated by the Applicant or Supplier.

Within the prescribed timeframe, the Approved Auditor shall complete their audit report and provide a recommendation to the Program Administrator as to whether the Approval Requirements are fulfilled. A copy of the audit report is also to be provided to the Applicant or Supplier within the prescribed timeframe.

The Program Administrator shall consider the audit report.

4.8 Nonconformities

During the evaluation and at other times the Program Administrator or Approved Auditor may raise nonconformities. These nonconformities can arise through the failure of the Applicant or Supplier to demonstrate their ongoing fulfilment of Approval Requirements, including in response to verified feedback, complaints or notifications from Suppliers of identified nonconformities. Nonconformities shall be categorised as specified in Annex A and recorded with any associated corrective actions by the Program Administrator or Approved Auditor.

The Program Administrator or Approved Auditor shall specify due dates for nonconformities to be resolved. Such timeframes shall be based upon guidance provided by the Program Administrator for maximum timeframes for nonconformity resolution.

The Applicant or Supplier shall respond with evidence that each nonconformity has been adequately resolved through appropriate corrective action by the specified due date.

If the Applicant or Supplier does not respond with sufficient evidence that the nonconformity has been resolved to the satisfaction of the Program Administrator or Approved Auditor by the specified due date, this shall be noted in the Audit Evaluation Report and:

a) in the case of an Applicant, approval not be granted; or

b) in the case of a Supplier:

   i. the nonconformity may be escalated in accordance with Annex A; or

   ii. approval may be suspended or withdrawn.

Where a nonconformity is raised against a Supplier, the Program Administrator shall, within the timeframes specified, inform the Standards Committee and state and territory jurisdictions of the:

a) identified nonconformity including all relevant detail relating to the:

   i. NLIS Approved Animal Identification Technology(ies) affected;

   ii. details of the Supplier;

   iii. manner in which the nonconformity was identified (e.g. surveillance audit, unscheduled audit, complaint or market feedback etc.);

iv. cause of the nonconformity;

v. the number of NLIS Approved Technology(ies) commercially available which may be affected;

vi. the number of orders that may contain one or more affected technologies;

vii. severity of nonconformity; and

viii. timeframe specified for corrective action; and

b) progress made by the Supplier towards closing out the nonconformity, including:

i. the corrective action taken by the Supplier to close out the nonconformity and, where necessary, the verification of such by an Approved Auditor; or

ii. the escalation of the nonconformity if it remains unresolved after the specified timeframe; and

iii. the intent to suspend or withdraw approval(s) from the Supplier of the NLIS Approved Technology(ies) due to the nonconformity.

Suppliers may raise nonconformities through their own management systems in a similar manner.

4.9 Audit Evaluation Reports

The Approved Auditor shall prepare an Audit Evaluation Report containing:

a) the findings in relation to the demonstrated fulfilment of each requirement;

b) any nonconformities along with any:

i. planned corrective actions;

ii. undertaken corrective actions; and

iii. evidence to demonstrate whether corrective action has been sufficient to close out the nonconformities.

c) a recommendation as to whether approval should be granted or declined, including any conditions.

The Audit Evaluation Report shall be submitted to the Program Administrator.

4.10 Field trials

Applicant's seeking experimental approval for an animal identification technology shall be required to undertake field trials as specified in Table 2 and in accordance with Annex B.

Table 2: Animal identification technologies requiring field trials

Species	Technology type	Field trial
Cattle	Electronic - RFID	Required
Sheep	Electronic - RFID	Required
	Non-electronic - Physical identification	Required
Goats	Electronic - RFID	Required
	Non-electronic - Physical identification	Required

The requirement to conduct a field trial as indicated in Table 2 or the duration or scope of a field trial, may be varied by the Program Administrator in consultation with the Applicant and Standards Committee.

Where field trials are to be conducted, the Program Administrator shall, within the timeframes specified, inform the relevant state and territory jurisdiction of the scope of the field trial.

4.11 Testing

The Program Administrator can conduct or request an Applicant or Supplier to conduct tests as applicable prior to making a decision to approve a technology. Testing can be electronic, chemical, physical or biological.

Test requirements shall be made available by the Program Administrator.

4.12 Decisions to grant approval or suspend or withdraw approval

An impartial party shall be appointed by the Program Administrator to consider whether to:

a) grant or decline:

   i. experimental approval to Applicant's seeking to undertake field trials as part of the process to acquire conditional approval;

   ii. conditional approval to Applicant's who have completed at least six months of any required field trials and have applied for conditional approval as part of the process to acquire full approval; or

   iii. full approval to:

      1) Applicants who have completed any required field trials and have applied for full approval;

      2) Suppliers who have been supplying conditionally approved technology for at least six months; or

      3) Suppliers who are seeking to renew their full approval; or

b) suspend or withdraw approval in accordance with section 11.

NOTE Impartial means that the party appointed has not been involved in the evaluation process prior to the decision and can be a party who is internal or external to the Program Administrator.

The impartial party shall:

a) consider all information submitted or created as a result of the evaluation process; and

b) provide their recommendation to the Program Owner within five days of concluding their deliberations.

In considering whether to grant approval, the Program Administrator shall provide to the Standards Committee for their consideration and determination:

a) the outcome of the impartial party's consideration;

b) the Applicant's application and supporting documentation;

c) the Audit Evaluation Report;

d) the report from a testing laboratory if commissioned by the Program Administrator;

e) for conditional approval, the:

   i. Field Trial Application Report; and

   ii. Field Trial Assessment Report – 6 Months; and

f) for full approval after the full period of field trials:

   i. the Field Trial Application Report;

   ii. the Field Trial Assessment Report – 6 Months, 12 Months, 24 Months and 36 Months;

   iii. the report from the biometrician if commissioned by the Program Administrator; and

   iv. a summary of complaints or nonconformities that have been raised since the granting of conditional approval.

NOTE Where field trial duration or scope has been varied then the associated reports shall be varied also.

The Standards Committee shall evaluate the information provided by the Program Administrator to support the application for approval and determine if the animal identification technology has demonstrated it fulfils the Approval Requirements. Their determination shall be provided to the Program Administrator.

In the event that the Standards Committee determines that the animal identification technology does not fulfil the Approval Requirements, the Standards Committee shall detail the requirements which are not fulfilled and the basis for their determination to the Program Administrator who shall inform the Applicant or Supplier.

In considering whether to suspend or withdraw approval, the Program Administrator shall provide to the Standards Committee for their consideration and determination:

a) the outcome of the impartial party's consideration;

b) any Audit Evaluation Report;

c) any report from a testing laboratory if commissioned by the Program Administrator;

d) for technologies with conditional approval, any Field Trial Assessment Reports; and

e) a summary of complaints or nonconformities that have been raised.

The Standards Committee shall evaluate the information provided by the Program Administrator and make a determination as to whether the NLIS Approved Technology should have its approval suspended or withdrawn. Their determination shall be provided to the Program Administrator.

In the event that the Standards Committee determines that the NLIS Approved Technology should have its approval suspended or withdrawn, the Standards Committee shall detail the basis for their determination to the Program Administrator who shall inform the Applicant or Supplier.

The final decision to grant, decline, suspend or withdraw experimental, conditional or full approval shall be made by the Program Administrator and communicated to the Applicant or Supplier, along with a specified timeframe within which the Applicant or Supplier may lodge an appeal against the decision. The decision, along with the rational for the decision will be communicated to the Standards Committee.

Approval is only for the features necessary to directly facilitate the primary purpose.

Applicants may, as an alternative to the lodging of an Appeal, reapply for approval if the previous application is not successful. Such repeat applications may be treated as entirely new applications and the full process may be repeated in each case, including the payment of any fees, charges and disbursements.

5 SURVEILLANCE

Suppliers shall be subject to periodic surveillance during the term of their approval which shall include:

a) an onsite audit at periodic intervals set by the Program Administrator;

b) ongoing monitoring of their NLIS Approved Technology available in the market to ensure it remains consistent with the NLIS Approved Technology samples held by the Program Administrator. Such monitoring shall include but not be limited to testing of samples taken:

   i. from throughout the supply chain at regular intervals; and

   ii. post-processing.

c) consideration of complaints and market feedback received by the Program Administrator in accordance with section 13;

d) notifications of major and critical nonconformities from Suppliers;

e) provision by the Supplier of all internal audit reports and external audit reports from certification bodies, to the Program Administrator within seven days of completion of those reports.

The processes detailed in section 4.7, 4.8 and 4.9 shall apply to periodic surveillance.

6 APPEALS

Appeals against decisions to decline, suspend or withdraw approval may be lodged with the Program Administrator. An appeal shall only be considered as being valid and properly executed if lodged in the prescribed format and within the prescribed timeframe.

The Program Administrator shall inform the Standards Committee when it receives any appeal.

The Program Administrator shall appoint at least three competent persons to form an Appeals Panel. The persons appointed to consider the appeal shall not have otherwise been involved in undertaking the evaluation, preparing the Evaluation Report, the decision making process to grant or decline approval or suspend or withdraw approval, and must not have had a relationship with the Applicant or Supplier within the previous 24 months (e.g. as a business associate, supplier, purchaser, relative, acquaintance, friend, partner, employee, volunteer, intern, contractor, advisor or consultant) that would give rise to a conflict of interest.

The Appeals Panel shall consider the merits of the appeal and make a final decision.

The Appeals Panel shall be entitled to call for all documentation prepared by the Program Administrator or Approved Auditor as well as all submissions made by the appellant.

The decision made by the Appeals Panel to dismiss or uphold the appeal shall be final and communicated in writing to the appellant and the Program Administrator by the Appeals Panel.

7 APPROVAL AGREEMENT, USE OF NLIS LOGO AND LABEL CLAIMS

At the end of the period for lodgement of an appeal after a decision to decline, suspend or withdraw approval, or after the outcome of an appeal is issued, if the decision is to grant approval, the Program Administrator shall issue an Approval Agreement which includes the NLIS Logo License.

The Program Administrator shall record the decision and update the Program Directory.

The Approval Agreement shall include the following information:

a) the name, description and dimensions of the NLIS Approved Technology;

b) images of the NLIS Approved Technology;

c) the date that approval is granted and a unique approval number;

d) the name and address of the Supplier;

e) the Scope of Approval including the type of Approval;

f) the product field code to be used by the Supplier on all NLIS database uploads for that NLIS Approved Technology;

g) the manner in which the NLIS Logo may be used;

h) any conditions placed on approval;

i) statements and label claims required for packaging; and

j) the validity period.

Approval Agreements remain the property of the Program Administrator.

The validity period of Approval Agreements may be for:

a) Experimental approval: Nine months

b) Conditional approval: Up to 36 months

c) Full approval: Up to five years.

The Program Administrator may, at its discretion, vary the validity period of Approval Agreements from those listed.

Suppliers holding conditional or full approval shall promote the fact that they are approved (i.e. make a 'label claim') on their communication and promotional materials and product packaging in accordance with Table 3; however, these claims shall not be placed directly on animal identification technology products.

Table 3: Statements required with a label claim

Approval status	Communications and promotional materials	Consumer packaging
Experimental	Nil	Nil
Conditional	**a) shall include:** i. 'NLIS Approved Animal Identification Technology (Conditional)'; or ii. 'NLIS Approved (Conditional)'; or iii. 'NLIS Approved Technology (Conditional)'; and iv. the statement: 'Subject to ongoing trialling by Integrity Systems Company Ltd.'; and **b) where the technology includes features which are not directly related to the primary purpose, shall include the statement:** i. 'Only the features necessary to facilitate the identification and traceability of animals under NLIS have been assessed and conditionally approved.'.	**a) shall include:** i. 'NLIS Approved Animal Identification Technology (Conditional)'; or ii. 'NLIS Approved (Conditional)'; or iii. 'NLIS Approved Technology (Conditional)'; and iv. the statement: 'To report any problems associated with the use of this technology under NLIS contact Integrity Systems Company Ltd. by phoning: xxxxxxx or email: xxx@xxx'; and **b) where the technology includes features which are not directly related to the primary purpose, shall include the statement:** i. 'Only the features necessary to facilitate the identification and traceability of animals under NLIS have been assessed and approved.'.
Full	**a) shall include:** i. 'NLIS Approved Animal Identification Technology'; or ii. 'NLIS Approved'; or iii. 'NLIS Approved Technology'. **b) where the technology includes features which are not directly related to the primary purpose, shall include the statement:** i. 'Only the features necessary to facilitate the identification and traceability of animals under NLIS have been assessed and approved.'.	**a) shall include:** i. 'NLIS Approved Animal Identification Technology'; or ii. 'NLIS Approved'; or iii. 'NLIS Approved Technology'; and iv. the statement: 'To report any problems associated with the use of this device under NLIS contact Integrity Systems Company Ltd. by phoning: xxxxxxx or email: xxx@xxx'; and **c) where the technology includes features which are not directly related to the**

		primary purpose, shall include the statement: i. 'Only the features necessary to facilitate the identification and traceability of animals under NLIS have been assessed and approved.'.

Incorrect references to the Program or Approval shall include, but shall not be limited to:

a) use of any marks or labelling on the animal identification technology other than that permitted by the Approval Requirements;

b) misleading use of the words prescribed in this section or in the Approval Agreement;

c) misleading claims regarding the efficacy of the NLIS Approved Technology; or

d) representation of approval under the Program as an endorsement of, or evidence regarding the efficacy of, any other feature of the technology not associated with the scope of the Program.

The Program Administrator shall investigate and action any occurrences of incorrect references. Failure to correct any incorrect references by any Applicant or Supplier may lead to approval not being granted, or suspension or withdrawal of an existing approval.

8 RENEWAL OF APPROVAL

Six months before the expiry date of approval as specified in the Approval Agreement, the Supplier shall:

a) make application to renew approval as provided in section 4.4; or

b) notify the Program Administrator of their voluntary withdrawal from the Program.

Renewal of approval shall follow the process contained in section 4, with the exception of section 4.2 and, provided the NLIS Approved Technology is verified as consistent with the samples held by the Program Administrator, section 4.10.

Where the Supplier does not undertake item a) or b) above and the expiry date specified in the Approval Agreement lapses, their Approval shall be withdrawn.

9 PROGRAM DIRECTORY

Only the fully executed copy of the Approval Agreement held by the Program Administrator is considered valid under the Program Rules.

The Program Administrator shall maintain a public Program Directory that shall contain at least the following information:

a) for all approval statuses:

   i. the name, address and Authorised Representative of each Applicant and Supplier;

   ii. the approval status of the NLIS Approved Technology (experimental, conditional, full, suspended, withdrawn or withdrawn - voluntary);

   iii. the name and dimensions of the NLIS Approved Technology;

   iv. the scope of approval; and

b) in addition, for conditional, full, suspended and withdrawn statuses:

   i. images of the NLIS Approved Technology.

In making an application to be approved, the Applicant agrees to the validity of any approval that they may hold being confirmed upon request.

10 CHANGES TO APPROVAL

Changes that may materially affect the Applicant or Supplier's ability to fulfil the Approval Requirements shall be made known to the Program Administrator prior to their occurrence for consideration. Changes that may materially affect the Applicant or Supplier's ability to fulfil the Approval Requirements include, but are not limited to:

a) any changes to the NLIS Approved Technology including any intent to substitute or change any of the components;

b) changes in the Approval Requirements;

c) changes in ownership or control of the Applicant or Supplier;

d) changes in business operations, including Supplier business structure, suppliers, purchasers, site relocations, major expansions or closures, compliance requirements;

e) changes in manufacturing processes;

f) changes in key personnel (i.e. board or top management or the equivalent);

g) major changes to the management system;

h) verified market feedback or complaints; and

i) any intention to voluntarily withdraw from approval.

After due consideration of the changes the Program Administrator may:

a) take no action;

b) require one or more steps in the evaluation process to be undertaken or reconfirmed, suitably modified in depth of detail to reflect the nature of the change;

c) require an alternative evaluation process to be undertaken;

d) reconfirm the current approval;

e) change the scope of the current approval;

f) order a partial or full recall of batches that may contain defective animal identification technologies;

g) suspend the approval; or

h) withdraw the approval.

11 RECALLS, SUSPENSION, WITHDRAWAL AND SANCTIONS

11.1 Recalls

The Program Administrator may instruct the Supplier to recall NLIS Approved Technologies, at the Supplier's cost. This may occur in relation to nonconformities being raised or suspension or withdrawal of approval.

Where a recall is required, the Supplier shall immediately:

a) submit to the Program Administrator for approval all communication regarding the recall the Supplier shall make with affected customers and supply chain participants;

NOTE Communication relates to the manner in which the recall is explained.

b) using the communication approved by the Program Administrator, issue a recall to its past and existing customers and supply chain participants that may be affected and whether the recall applies to:

i. unused technologies; or

ii. technologies currently applied to livestock; or

iii. both; and

c) undertake any other such action requested by the Program Administrator.

Following the recall process being initiated, the Supplier shall provide a report to the Program Administrator in the specified timeframe which includes:

a) an overview of the recall process;

b) the communication provided to customers and supply chain participants;

c) any feedback received; and

d) how many of the affected technologies have been returned;

11.2 Suspension of approval

For situations where the Supplier cannot demonstrate ongoing fulfilment of Approval Requirements, the Program Administrator may suspend the approval of a Supplier's NLIS Approved Technology.

Examples of situations which can result in suspension include, but are not limited to:

a) identification of critical nonconformities, which, in the opinion of the Program Administrator and the Standards Committee represent a serious risk to the integrity of NLIS or the Program;

b) failure to close out nonconformities within specified timeframes and in accordance with section 4.8 and Annex A;

c) failure to respond within the prescribed timeframe to notices and directions of the Program Administrator or Approved Auditor;

d) failure to demonstrate fulfilment within the prescribed timeframe of changes to the Approval Requirements;

e) failure to renew approval within the specified timeframe;

f) failure to notify the Program Administrator of any material changes to approval in line with section 10; and

g) ongoing failure to demonstrate that the causes of repeated nonconformities are being addressed.

The Program Administrator shall notify the Supplier of the:

a) suspended status;

b) the technology which has had its approval suspended;

c) the reason for the suspension; and

d) follow up actions, including recalls, that are required within specified timeframes.

Decisions to suspend approval may be appealed in accordance with section 6 however, the suspension shall stand until the appeals process has resolved.

In cases of suspension, the Supplier shall, immediately:

a) cease production and supply of the suspended technology;

b) discontinue all references to the approval status for that suspended technology, including removing any such references from websites, marketing material or other communications;

c) submit to the Program Administrator for approval all communication regarding the suspension of approval the Supplier shall make with customers and supply chain participants;

NOTE Communication relates to the manner in which the suspension of approval is explained.

d) using the communication approved by the Program Administrator, inform its past and existing customers and supply chain participants:

i. that the approval for that technology is suspended;

ii. how they can transition to an alternative NLIS Approved Technology if necessary; and

iii. undertake any other such action requested by the Program Administrator.

11.3 Withdrawal of approval

11.3.1 Involuntary withdrawal

The Program Administrator may withdraw approval of an NLIS Approved Technology where the Supplier of that NLIS Approved Technology:

a) does not satisfactorily respond to a suspension within the specified timeframe;

b) holds conditional approval but does not continue to meet the requirements provided in Annex B during field trial assessments;

c) supplies animal identification technologies (whether NLIS Approved Technology or not) to the market which critically nonconform with the Approval Requirements, or in the opinion of the Program Administrator and the Standards Committee, represent a serious risk to the integrity of NLIS or the Program;

d) becomes insolvent;

e) is involved in activities that are fraudulent, dishonest, criminal or bring the Program and /or the industries relying on animal identification technologies into disrepute; or

f) where there is credible evidence that the Supplier's NLIS Approved Technology threatens the integrity and purpose of NLIS or the Program.

The Program Administrator shall notify the Supplier of NLIS Approved Technology of:

a) the withdrawn status;

b) the NLIS Approved Technology which has had its approval withdrawn;

c) the reasons for the withdrawal; and

d) any requirement to, at the cost of the Supplier, issue an immediate recall to past and present customers and supply chain participants and whether that recall applies to:

i. unused technologies; or

ii. technologies currently applied to livestock; or

iii. both.

Decisions to withdraw approval may be appealed in accordance with section 6 however, the withdrawal shall stand during the appeal process.

In cases of withdrawal, the Supplier of the technology which has had its approval withdrawn shall, immediately:

a) cease production and sale of the technology which has had its approval withdrawn;

b) discontinue all references to the approval status for the technology which has had its approval withdrawn, including the removal of any such references from websites, marketing material or other communications;

c) submit to the Program Administrator for approval all communication regarding the withdrawal of approval the Supplier shall make with customers and supply chain participants;

NOTE Communication relates to the manner in which the withdrawal of approval is explained.

d) inform its past and existing customers and supply chain participants that may be affected:

i. that approval for that technology has been withdrawn; and

ii. how they can, at the cost of the Supplier:

1) return for replacement or refund any technology which has had its approval withdrawn which are unused or currently applied to animals; and

2) transition to an alternative NLIS Approved Technology if necessary; and

e) undertake any other such action requested by the Program Administrator.

11.3.2 Voluntary withdrawal

A Supplier may, by way of written notice to the Program Administrator, request withdrawal of approval of their NLIS Approved Technology at any time.

Voluntary withdrawal is effective upon confirmation by the Program Administrator of the change in status. Where a Supplier voluntarily withdraws approval, application may be made at any time for reinstatement of approval for the same animal identification technology originally approved. The Program Administrator, in consultation with the Standards Committee shall consider and inform the Supplier which parts of section 4 shall be applicable in considering the reinstatement of approval.

In cases of voluntary withdrawal, the Supplier of NLIS Approved Technology shall, immediately:

a) cease production and sale of that technology which has had its approval withdrawn;

b) discontinue all references to its approval status for that animal identification technology, including the removal of any such references from websites, marketing material or other communications; and

c) undertake any other such action requested by the Program Administrator.

11.3.3 Continued record keeping

For a period of eight years from when approval was first granted, Suppliers with withdrawn approval shall:

a) maintain records as required under the Approval Requirements and in accordance with any compliance requirements;

b) provide access to such records to the Program Administrator upon request; and

c) notify the Program Administrator should any issues with the withdrawn technology, which has not been subject to a recall, arise.

NOTE Should compliance requirements stipulate records to be kept for longer than eight years then those compliance requirements shall prevail.

11.4 Sanctions

The Program Administrator may apply sanctions to Suppliers as opposed to or in conjunction with nonconformities, corrective action, recalls, suspension or withdrawal.

12 FEES AND CHARGES

Fees and charges associated with the Program shall be determined by the Program Administrator.

Applicants and Suppliers are responsible for paying the fees and charges that have been approved by the Program Administrator.

The issuance of an Approval Agreement shall not be undertaken until all outstanding fees and charges have been paid.

13 COMPLAINTS AND MARKET FEEDBACK

13.1 Complaints - general

There are several types of complaints recognised under the Program as follows:

a) complaints received by Applicants or Suppliers from customers, stakeholders or the public regarding their animal identification technology or production processes;

b) complaints received by the Program Administrator, normally by customers, stakeholders or the public, about Applicants or Suppliers and their animal identification technology or production processes;

c) complaints received by the Program Administrator, Field Trial Supervisors or Approved Auditors from Applicants or Suppliers, or other parties, regarding the performance of the Program Administrator, Field Trial Supervisors or Approved Auditors, or any of their personnel; or

d) misrepresentation of Approvals.

Complaints relating to types b), c) and in some cases d), may result in:

a) the raising of nonconformities against a Supplier in accordance with section 4.8;

b) suspension of approval in accordance with section 11.1; or

c) withdrawal of approval in accordance with section 11.3.

A complaint shall be deemed to have been received by the Applicant or Supplier or Program Administrator when:

a) a complaint has been submitted by the complainant in writing or by telephone call;

b) the complainant has given full details of their name, address, contact details, and information regarding any previous or existing involvement with the party that they are complaining about;

c) the nature of the complaint corresponds to one of the categories listed above and is directly related to the non-fulfilment of Approval Requirements; and

d) the complainant can provide details in relation to the basis of the complaint.

All complaints shall be acknowledged and addressed in a timely manner.

13.2 Complaints handling procedure

Applicants, Suppliers and the Program Administrator shall have a complaint's handling procedure:

a) in place;

b) publicly available; and

c) which draws on relevant components of ISO 10002:2018 *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations.*

13.3 Complaints received by Applicant or Supplier

Applicants or Suppliers shall maintain a complaint register to record all complaints. All registered complaints shall be dealt with in terms of the Applicant or Supplier's procedures that shall provide for the investigation and resolution of the complaint and, as necessary, undertaking corrective action.

Applicants or Suppliers shall inform the complainant of the outcome of the complaint in a timely manner.

Records of complaints as well as the handling of complaints by the Applicant or Supplier shall be provided to the Program Administrator when received and made available for review during evaluation. The Program Administrator reserves the right to undertake its own enquiries and investigations at any time.

13.4 Complaints received by the Program Administrator about an Applicant or Supplier

In the first instance the Program Administrator will endeavour to identify and direct the complaint to the relevant Applicant or Supplier for resolution in accordance with sections 13.2 and 13.3. In doing so, the Program Administrator shall retain oversight of the compliant and require the Applicant or Supplier to provide regular updates on the progress of investigating and resolving the complaint.

Where the complainant is dissatisfied with the response, or if the Program Administrator is concerned about the Applicant or Supplier's adherence to the Approval Requirements or progress towards resolving the complaint, the Program Administrator may investigate the complaint further. This investigation may include requesting further information from the Applicant or Supplier or undertaking further evaluation activities.

In instances where the complainant and the Applicant or Supplier is unable to resolve the matter amongst themselves and the complainant refuses to withdraw the complaint, the Program Administrator shall investigate the complaint.

The Applicant or Supplier shall be responsible for paying all fees, charges and disbursements incurred by the Program Administrator that are directly associated with the investigation of complaints.

Where a complaint is raised against a Supplier which may relate to a major or critical nonconformity, the Program Administrator shall, within the timeframes specified:

a) inform the Standards Committee and state and territory jurisdictions of the:

iv. NLIS Approved Animal Identification Technology(ies) affected;

v. details of the Supplier;

vi. manner in which the complaint was provided;

vii. details of the complaint and any evidence provided; and

viii. progress made towards investigating the complaint; and

b) inform the Standards Committee and state and territory jurisdictions updated of the progress of the investigation and resolution of the complaint.

13.5 Complaints about the Program Administrator, Field Trial Supervisor, Field Trial Participant or Approved Auditor

Complaints received by the Program Administrator in relation to the Program, including the execution and conduct of duties and responsibilities of Field Trial Supervisors, Field Trial Participants or Approved Auditors in relation to approval activities (including complaints received in relation to any personnel appointed by the Program Administrator), shall be investigated by the Program Administrator's Chief Executive or delegate. If complaints are considered valid and appropriate, such complaints shall be referred to the Program Administrator, Field Trial Supervisor, Field Trial Participant or Approved Auditors for implementation of corrective action in accordance with their internal procedures.

Complaints received by the Program Administrator in relation to its own duties and responsibility under the Program shall be referred to Program Owner.

13.6 Complaints about the misrepresentation of Approval

Complaints received by the Program Administrator in relation to misrepresentation of Approval shall be investigated by the Program Administrator in accordance with their complaints procedures.

13.7 Market feedback

The Program Administrator shall establish processes for receiving passive or solicited feedback from supply chain participants and other key stakeholders regarding the performance of NLIS Approved Technologies available commercially in the market.

Such feedback shall be considered by the Program Administrator in a similar manner to complaints.

14 CONFIDENTIALITY, COMMUNICATIONS AND NOTICES

14.1 Confidentiality

All parties to the Program shall have legally enforceable agreements with all internal and external personnel (including any committees) to maintain all information associated with the Program and evaluation activities as confidential, except for the following:

a) information that is submitted and transferred between the parties in order to operate the Program. The parties referred to in this subclause are personnel of:

   i. the Program Administrator;

   ii. the Standards Committee;

   iii. the Field Trial Supervisors;

   iv. the Field Trial Participants;

   v. Approved Auditors;

   vi. Applicants and Suppliers for information relating only to their own applications and approvals; and

   vii. organisations involved in any testing commissioned by the Program Administrator;

   viii. any organisation involved in the evaluation, approval, peer assessment or other form of third-party recognition that the Program Administrator has agreed to adopt;

b) upon request, the confirmation of the validity of the status of an Applicant or Supplier of NLIS Approved Technology; and

c) any information that the Program Administrator or the Approved Auditors must disclose as required by the law, and in which case prior to such release of such information the Program Administrator or Approved Auditor shall inform the relevant Applicant or Supplier of the intent to disclose that information.

All audit reports and outcomes and field trial reports, data and outcomes shall remain the property of the Program Administrator and shall be:

d) kept confidential;

e) released to the Supplier; and

f) released to other parties as required to determine approval, or where required by law.

Information held by the Program Administrator may be released upon prior approval of the Supplier.

14.2 Communications

The Program Administrator shall be responsible for the preparation and release of information about the Program.

Subject to the payment of any relevant fee and any other conditions, the Program Administrator shall make available to the public the following information:

a) the Approval Requirements;

b) information about the fees and charges;

c) guidelines on maximum timeframes for closing out minor, major and critical nonconformities; and

d) information on handling complaints and appeals.

Subject to the payment of any relevant fee and any other conditions, the Program Administrator shall make available to the parties under this Program the following information as necessary and relevant:

a) the Approval Requirements;

b) appropriate forms, templates, guidance documents, etc.; and

c) arrangements associated with changes to the Approval Requirements, including deadlines for transition.

14.3 Notices

All parties to the Program shall nominate and maintain a formal Authorised Representative who is responsible for the receipt and transmission of all formal communication between the parties.

Each party shall be responsible for providing the up-to-date name and contact details of the Authorised Representative to the Program Administrator. A list of Authorised Representatives shall be kept and maintained by the Program Administrator.

Formal communications between the parties shall be addressed to the Authorised Representative and shall be in writing and transmitted through traditional mail or email. The Program Administrator may utilise electronic communication (for example using emails or internet notifications) to convey formal communications.

15 PROGRAM OVERSIGHT AND REVIEW

The Program Administrator shall establish a mechanism to review, at least once every three years, the:

a) performance of appointed Field Trial Supervisors, Field Trial Participants and Approved Auditors;

b) oversight of the operation of the Approval Program; and

c) Approval Requirements.

The Program Administrator in consultation with the Standards Committee, where necessary, has the right to recommend amendments, deletions, additions or any other changes which it may deem necessary to the Approval Requirements to the Program Owner. Any proposed amendments shall be made in accordance with the Program Administrator's procedures and completed following due process, including consultation with the Standards Committee and with Suppliers.

The Program Administrator shall communicate any amendments, additions, deletions or other changes to the Field Trial Supervisors, Field Trial Participants, Approved Auditors, Applicants and Suppliers, including any specified transition period or specified timeframe for fulfilment. Generally, any such changes shall not be retrospectively applied.

16 GOVERNING LAW

All legally enforceable agreements between the parties are to be construed as in accordance with, and any matter related are to be governed by, the laws of New South Wales, Australia, and the parties submit to the non-exclusive jurisdiction of the courts of New South Wales, Australia.

17 DOCUMENT CONTROL

Most recent version	Operative Date	Summary of changes from last version	Approved by
2.0	29/06/2023	Adjustments based on comments received from jurisdictions and peak industry councils on Standards Committee Terms of Reference.	SAFEMEAT
1.0	21/10/2020	Updating final draft with minor edits. Program endorsed by SAFEMEAT December 2020.	SAFEMEAT

ANNEX A: Nonconformities

(normative)

A.1 Definitions of nonconformities

The following categories of nonconformities shall be applicable under the Program:

Critical

a) a nonfulfillment of a requirement that prevents the Applicant or Supplier from achieving the intended outcomes which:

   i. results in or has the potential to result in systemic, large scale loss of animal traceability under NLIS;

   ii. presents a serious risk to Australia's animal traceability systems; or

   iii. causes serious, large scale, adverse animal welfare outcomes;

b) if there is an absence of an effective production process control, or the production process controls repeatedly fail to ensure the associated requirements are fulfilled;

c) a systematic and repeated failure to identify or acknowledge nonconformities and undertake corrective actions;

d) a number of major nonconformities associated with the same approval requirement or issue that could demonstrate a systemic failure and thus constitute a critical nonconformity; or

e) a major nonconformity for which the Applicant or Supplier has failed to resolve within the prescribed timeframe.

Major

a) a non-fulfilment of a requirement that adversely affects the Applicant or Supplier achieving the intended outcomes which:

   i. results in or has the potential to result in large scale loss of animal traceability under NLIS;

   ii. presents a serious risk to Australia's animal traceability systems; or

   iii. causes adverse animal welfare outcomes;

b) a failure to identify or acknowledge nonconformities and undertake corrective actions;

c) a number of minor nonconformities associated with the same approval requirement or issue that could demonstrate a systemic failure and thus constitute a major nonconformity; or

d) a minor nonconformity for which the Applicant or Supplier has failed to resolve within the prescribed timeframe.

Minor

a) a non-fulfilment of a requirement that does not affect the capability of the Applicant or Supplier to achieve the intended outcomes.

A.2 Assigning nonconformities

The framework for determining the severity of nonconformity is provided in Table A-1 which considers the impact and the number of instances of the nonconformity. The severity of nonconformity raised is at the discretion of the Approved Auditor and the Program Administrator.

Table A-1 Framework for assigning nonconformities

	Infrequent	Numerous	Systemic
High traceability impact	Major	Major	Critical
Moderate traceability impact	Major	Major	Critical
Animal welfare impact	Minor	Major	Critical
Management system/ paperwork	Minor	Major	Critical

Each nonconformity is evaluated based on the matrix above to determine the severity of the nonconformity taking into account the specific circumstances witnessed by the Approved Auditor or as a result of customer feedback or complaints.

The meanings of the impacts and number of instances included in the matrix are provided as follows:

a) high traceability impact - circumstances in which:

   i. animals cannot be traced;

b) moderate traceability impact - circumstances in which:

   i. animals can still be traced;

c) animal welfare impact – relates to a direct adverse impact the animal identification technology has on the welfare of an animal;

d) management system/paperwork - related to management system or paperwork (e.g. records, documented procedures) but excludes system or paperwork related to traceability;

e) infrequent - a small number of occurrences:

   i. for which a procedure is in place to prevent occurrence; or

   ii. management intervention occurs and corrective action is applied;

f) numerous - more than one animal, unit, order, or batch or multiple occurrences:

   i. for which a procedure is in place to prevent occurrences; or

   ii. management intervention occurs but only after multiple occurrences and corrective action is applied;

g) systemic - occurs (may only occur once) but is widespread; affecting or relating to a group of animals or units, an order, a batch and:

   i. the occurrence seriously jeopardises the primary purpose;

   ii. no system is in place to prevent ongoing occurrence, allowing for systemic failure; or

   iii. no management intervention occurs or corrective action is applied; or

   iv. the issue is ingrained in the behaviour of personnel or within the system; or

   v. management believes the behaviour is acceptable and takes no action to resolve; or

   vi. corrective action only occurs after identification by another party.

ANNEX B: Field Trial Protocols for Animal Identification Technologies

(normative)

B.1 Purpose

This protocol was developed for Applicants who require field trials to be undertaken as part of the process of gaining conditional or full approval. In seeking such approval, field trials shall be undertaken and assessed following these protocols and the results of the trials will form part of the evaluation process.

The Program Administrator is responsible for coordinating, administering and overseeing field trials and reserves the right to interpret the data and determine approval or otherwise, based on its judgment of the results. The Standards Committee supports the oversight of field trials and considers the outcomes of the field trial assessment as part of the decision made under section 4.12.

The key elements to be assessed and documented through the field trial process are:

a) application

b) retention (i.e. physical loss);

c) durability and structural integrity (i.e. physical deterioration of print and materials);

d) readability; and

e) animal welfare impacts.

B.2 Field trial design principles

Field trials shall be practical so that Field Trial Participants can integrate them into normal husbandry and herd or flock management operations. This encourages Field Trial Participants to retain in their herds or flocks enough livestock fitted with trial animal identification technologies for the duration of the trial.

Trials shall be conducted in compliance with compliance requirements. The Program Administrator takes no responsibility and accepts no liability for any losses or injury to livestock or personnel associated with animal identification technology field trials. The Program Administrator takes no responsibility and accepts no liability if a participating Field Trial Participant sells or moves trial animals, or inadvertently or deliberately removes trial devices, or if trial animals die for any reason during the course of a trial.

Field trials will typically run for at least 36 months. To facilitate the early entry of animal identification technologies with credible performance characteristics to the Australian market, the Program Administrator may grant conditional approval after evidence is presented that the animal identification

technology has demonstrated ongoing conformity with the Approval Requirements after a minimum of six months of field trials.

Any animal identification technology approval based on a shorter timeframe than 36 months may be withdrawn if the actual performance of the animal identification technology over the period of the trial falls below the Approval Requirements.

B.3 Assumptions

The following assumptions were made in developing this field trial protocol:

a) Animal identification technology retention and readability shall be assessed on an individual animal basis. The outcome shall be a success or a failure. Each animal and accompanying animal identification technology shall only be considered as either a single success or failure depending on the results recorded throughout the trial.

b) Electronic animal identification technologies using low frequency RFID:

   i. shall be individually machine-read using:

      1) both:

         A. a commercially available single panel reader affixed (moveable is acceptable) to the (inside) right side of or above a crush, weigh box, ramp or race; and

         B. a commercially available handheld reader; and

      2) readers which have been confirmed as operating within the bandwidths defined in AS5019-2001, specifically within the transponder response frequency of 124.2 +/- 2.0kHz for Binary 1 and 134.2 +/- 1.5kHz for Binary 0; and

   ii. shall be assessed using readers at each assessment:

      1) in a walk-through situation;

      2) based on at least one assessment conducted using a panel reader; and

      3) in a manner which allows each animal to move freely past a reading point in a single file.

c) Non-electronic animal identification technologies using physical identification shall be visually read.

d) Confounding factors may affect animal identification technology retention on a particular property and the Program Administrator may assess these factors on application.

e) Retention rates shall be calculated based on the number of animals presented for reading at periodic assessments. Animal identification technology loss may be highest soon after application; however, loss rates should then stabilise for the remainder of the three-year trial. Losses may be higher for animal identification technologies attached to bulls, bobby calves, rams, lambs, bucks and kids.

f) Sales, deaths, natural disasters and factors out of the control of the Applicant or Field Trial Participant shall be accounted for.

g) Where such events occur as described in f), or if issues unrelated to the technology arise which may impact the viability of the field trial, the Program Administrator shall work with the Applicant and the Standards Committee to agree a suitable solution which addresses the event or issue.

h) During each assessment, the total number of animals in the herd or flock subject to the trial shall be recorded. Where numbers vary from the number of animals present for application and any previous assessments:

   i. a reasonable explanation shall be provided by the Field Trial Participant and noted on the Field Trial On-Farm Assessment Record; and

   ii. where animals have been sold, movements off the Field Trial Property shall be verified by the Field Trial Supervisor on the NLIS database and recorded in the Field Trial Assessment Report.

i) The final assessment for each animal in the field trial shall be undertaken approximately 36 months after application of the animal identification technology to that particular animal.

j) Failure of an animal identification technology to be read should be a rare event and occur at a relatively constant rate during the trial.

k) During field trials, standard operating procedures relating to on-farm traceability shall occur, including notifying the NLIS database of livestock movements. The Field Trial Supervisor shall verify all livestock movements off the property on the NLIS database.

l) The Program Administrator, in consultation with the Standards Committee, reserves the right to vary the scope or duration of a field trial.

B.4 Pre-field trial request

Applicants shall submit a request to conduct a field trial to the Program Administrator at least six weeks in advance of the proposed commencement of a field trial.

In submitting a request, the Applicant shall provide a field trial plan which details:

a) the type of animal identification technology to be trialled;

b) the animal species to be identified;

c) the method of cross referencing between the trial animal identification technology and a uniquely numbered reference animal identification method;

d) the name and contact details of the Applicant's personnel responsible for the field trial; and

e) the name and contact details of any person who may attend field trial assessment activities on the Applicant's behalf.

Within six weeks of receiving the submission, the Program Administrator shall:

a) appoint one or more Field Trial Properties to the Applicant;

b) appoint one or more Field Trial Supervisors to the Applicant;

c) notify the Applicant of the:

   i. location of the Field Trial Properties;

   ii. number, breed and age of the animals to be identified;

   iii. period of time over which initial application of the technology will occur; and

   iv. dates of application of the technology to livestock on each Field Trial Property; and

d) notify the appropriate jurisdictional representative of the intent to conduct a field trial.

At least five working days prior to the application of the technology to the first animal, the Applicant shall provide the Program Administrator with an electronic file listing the unique numbers associated with the animal identification technology to be used on each Field Trial Property.

The Program Administrator shall provide the appropriate jurisdictional representative with the electronic file listing the unique numbers associated with the animal identification technology to be used in the trial.

B.5 Establishing the field trial

Selection of Field Trial Properties

The Program Administrator shall maintain an ongoing, transparent expressions of interest process for Field Trial Properties and maintain a pre-approved panel of Field Trial Properties. At least annually, the Program Administrator shall publicise the call for expressions of interest. Requirements for Field Trial Properties shall include:

a) properties with a substantial breeding herd;

b) properties that are representative of a range of typical Australian animal husbandry practices and environments, in particular those characteristics represented in Table B-1;

c) the ability to access both types of readers required for use at each assessment;

d) the ability of the Field Trial Participant to:

i. gather and accurately record the information required;

ii. on each occasion that animal identification technology performance is assessed, reconcile the trial animal identification technology with the reference animal identification; and

iii. routinely account for all the identified animals; and

iv. maintain the appropriate number of identified animals on the property during the period of the field trial, as specified in Table B-1.

NOTE It is preferable that higher percentages of identified animals are retained at the 36-month assessment as this reduces the upper 95% confidence interval target. This can be achieved by identifying existing breeders as well as animals to be turned-off or used as replacements, or by selectively using a higher proportion of female animals likely to be used as replacements for culled breeders.

Upon receipt of an application for field trial, the Program Administrator shall make an assessment of the scope of the trial and identify and secure appropriate Field Trial Properties from the pre-approved panel. The Program Administrator may, before or during a field trial:

a) remove a Field Trial Property from the field trial; or

b) add a new Field Trial Property from the pre-approved panel to the field trial.

Should an Applicant want a new Field Trial Property from the pre-approved panel to be included in the field trial after it has commenced, they may make application to the Program Administrator.

Where a new Field Trial Property has been added to the field trial, the Program Administrator reserves the right to consider the performance of the animal identification technology across all Field Trial Properties involved, regardless of whether they remain in the field trial or not.

At the discretion of the Program Administrator, its representatives may attend any of the application and assessment events during the field trial.

Suppliers may attend application and assessment events with prior written approval from the Program Administrator.

Table B-1: Characteristics for Field Trial Properties

<table>
<tr><th>Species and technology type</th><th>Minimum number of different properties</th><th>Enterprise type</th><th>Location</th><th>Production system</th><th>Minimum number of livestock to be identified</th></tr>
<tr><td rowspan="3">Cattle

Electronic identification - RFID</td><td rowspan="3">3 – where fencing and yard construction is different between the properties</td><td>1 x dairy property</td><td></td><td>Pasture based only</td><td rowspan="3">1200
Recommended minimum per property: 300

Application should occur at marking</td></tr>
<tr><td rowspan="2">2 x beef properties</td><td>1 x northern</td><td>Open range pastoral zone with predominantly Bos indicus breeds or Bos indicus/Bos taurus cross breeds</td></tr>
<tr><td>1 x southern</td><td>Intensive pastoral zone with predominantly Bos taurus breeds</td></tr>
<tr><td rowspan="4">Sheep

Electronic identification - RFID</td><td rowspan="4">4 – where fencing and yard construction is different between the properties</td><td>1 x meat</td><td>Northern and western regions</td><td>Open range</td><td rowspan="4">1600
Recommended minimum per property: 400

Application should occur at marking</td></tr>
<tr><td>1 x Merino wool</td><td>Southern region</td><td>Intensive</td></tr>
<tr><td>1 x composite ewe flock</td><td>Any</td><td>Either open range or intensive</td></tr>
<tr><td>1 x any additional as above</td><td>Any as above</td><td>Any as above</td></tr>
<tr><td rowspan="3">Sheep

Non-electronic identification - Physical identification</td><td rowspan="3">3 – where fencing and yard construction is different between the properties</td><td>1 x meat</td><td rowspan="3">Southern and northern regions</td><td rowspan="3">Combination of open range or intensive</td><td rowspan="3">750
Recommended minimum per property: 250

Application should occur at marking</td></tr>
<tr><td>1 x Merino wool</td></tr>
<tr><td>1 x cross-bred lambs</td></tr>
<tr><td rowspan="2">Goats</td><td rowspan="2">3 – where fencing and yard construction</td><td>1 x meat</td><td rowspan="2">Any</td><td rowspan="2">Combination of:
Rangeland production
Managed production</td><td rowspan="2">750</td></tr>
<tr><td>1 x fibre</td></tr>
</table>

Electronic identification - RFID	is different between the properties	1 x dairy			Recommended minimum per property: 250 Application should occur at marking
Goats Non-electronic identification - Physical identification	3 – where fencing and yard construction is different between the properties	1 x meat	Any	Combination of: Rangeland production Managed production	750 Recommended minimum per property: 250 Application should occur at marking
		1 x fibre			
		1 x dairy			

NOTE 1 TO TABLE B-1 Open range production systems refer to large-scale farming/grazing operations predominantly grazing native or improved pastures. Properties are most likely found in the northern and western regions of Australia.

NOTE 2 TO TABLE B-1 Intensive production systems refer to smaller-scale specialised or mixed farming operations, possibly including enterprises which supplementary feed or intensively graze improved pastures. Properties are most likely found in southern regions of Australia.

NOTE 3 TO TABLE B-1 Rangeland production systems refer to those which capture goats from a wild state and therefore have not been born as a result of a managed breeding program and have not been subjected to any animal husbandry procedure or treatment. Rangeland goats may be captured and consolidated prior to sale.

NOTE 4 TO TABLE B-1 Managed production systems refer to those with deliberately managed breeding or husbandry programs.

NOTE 5 TO TABLE B-1 If the turn-off of livestock is likely to be high during the Field Trial then more animals than the minimum number specified shall be identified at the commencement of the trial.

NOTE 6 TO TABLE B-1 It is recognised that securing the minimum number for goats may be difficult. The Program Administrator may consider an alternative field trial scope for goats upon application by a Supplier and in consultation with the Standards Committee.

NOTE 7 TO TABLE B-1 Where infrastructure is used on dairy properties for supplementary feeding (e.g. stall feeders), the presence of such should be recorded by the Field Trial Supervisor.

Appointment of Field Trial Supervisors

The Program Administrator shall maintain an ongoing, transparent expressions of interest process for Field Trial Supervisors and maintain a pre-approved panel of Field Trial Supervisors. At least annually, the Program Administrator shall publicise the call for expressions of interest.

The Program Administrator shall appoint one or more Field Trial Supervisors from the pre-approved panel to the field trial. The Field Trial Supervisor appointed shall have no conflicts of interest with either the Field Trial Participant or the Applicant which could interfere with them performing their duties.

The Field Trial Supervisor shall attend each Field Trial Property for application and progressive assessment of animal identification technology performance. Different Field Trial Supervisors may attend different Field Trial Properties in the same field trial provided that a Field Trial Supervisor has assessed the initial application of animal identification technologies to the animals and all progressive assessments.

Record keeping

Field Trial Participants shall:

a) complete usual on-farm records and keep copies of these as specified by compliance requirements;

b) record all movements of livestock off the Field Trial Property that are subject to the field trial on the NLIS database;

c) immediately notify the Field Trial Supervisor of all movements of livestock off the Field Trial Property that are subject to the field trial along with the animals' intended destination;

d) immediately notify the Field Trial Supervisor of any potential issues with the field trial, including issues related to the welfare of animals with trial technology applied;

e) complete the Field Trial On-Farm Assessment Record during usual husbandry procedures;

f) submit the Field Trial On-Farm Assessment Record to the Program Administrator within five working days of completion; and

g) keep Field Trial On-Farm Assessment Records for the duration of the field trial.

Field Trial Supervisors shall:

a) complete and sign the Field Trial Application Report when the animal identification technology is first applied to livestock;

b) complete and sign the Field Trial Assessment Report during the progressive assessment periods;

c) verify any movements of livestock off the Field Trial Property subject to the field trial on the NLIS database;

d) immediately notify the Program Administrator of all movements of livestock off the Field Trial Property that are subject to the field trial, along with the animals' intended destination;

e) notify the Program Administrator of any issues which have been raised by the Field Trial Participant in relation to the field trial;

f) attend the property outside of the specified assessment periods where the Program Administrator determines there is cause to investigate potential issues with the field trial;

g) submit the field trial reports, including the scan read from the trial to the Program Administrator within five working days of completion; and

h) keep field trial reports for the duration of the trial.

The Program Administrator shall:

a) ensure all reports are collected from Field Trial Participants and Field Trial Supervisors as scheduled;

b) record the field trial results in a central database;

c) provide a copy of field trial reports and the scan read from the trial to the Applicant within seven days of receiving them;

d) provide a summary of field trial reports to the Standards Committee as necessary; and

e) keep the field trial reports collectively for a minimum of eight years.

B.6 Assessment of animal identification technologies

Animal identification technologies shall be subject to formal, progressive assessments by a Field Trial Supervisor at:

a) application;

b) six months;

c) 12 months;

d) 24 months; and

e) 36 months.

The Program Administrator may require additional assessments to be undertaken if necessary and shall also consider requests for additional assessments from Field Trial Participants, Applicants or Field Trial Supervisors provided they provide a request in writing at least 10 working days before the proposed assessment date. The occurrence of an additional assessment does not negate the need for the scheduled assessment to occur.

The Program Administrator shall make the necessary arrangements for the assessment between the Field Trial Supervisor and the Field Trial Participant and inform the Applicant of the arrangements.

It is recognised that due to specific husbandry practices on Field Trial Properties, the timing of assessments may vary. If it is not possible to assess the trial animal identification technology on a Field Trial Property, the Program Administrator shall consider those circumstances which are the cause of the missed assessment and may consider alternative arrangements such as extending the trial beyond 36 months.

Field Trial Participants are encouraged to continue monitoring animal identification technology performance after the 36-month trial and to provide results to the Program Administrator. The Program Administrator may contact Field Trial Participants in relation to animal identification technology performance after the 36-month trial.

B.7 Conducting the field trial

Assessment of application of the animal identification technology

At the commencement of the field trial, the animal identification technology shall be applied to the animals by the Field Trial Participant in accordance with the instructions provided and following adequate demonstration by the Applicant, where present. Where the animal identification technology is designed to be applied to an animal's ear, and the position of the animal identification technology is not specified by compliance requirements, then it shall be applied as specified in Table B-2.

At application, a uniquely numbered reference animal identification shall be applied to animals and cross-referenced to the trial animal identification technology to allow the Field Trial Supervisor to establish with certainty those animals in the trial and those animals which have lost their animal identification technology. The method of cross referencing between the trial animal identification technology and the reference animal identification shall be that described in the field trial plan. The trial animal identification technology and reference animal identification shall be correlated (including, where possible, with data from the NLIS database) and provided to the Program Administrator within five working days of application.

Table B-2: Application of animal identification technology designed to be applied to an animal's ears

	Technology type	Placement – trial animal identification technology	Placement – reference animal identification
Cattle	Electronic - RFID	Right ear	Left ear
Sheep	Electronic - RFID	Either ear	Opposite ear
	Non-electronic - Physical identification	Alternating ears	
Goats	Electronic - RFID	Either ear	Opposite ear
	Non-electronic -Physical identification	Alternating ears	

NOTE 1 TO TABLE B-2 For trial electronic animal identification technologies using RFID transponders other than that equivalent to the benchmark transponder, then the reference animal identification may be an NLIS Approved Technology.

NOTE 2 TO TABLE B-2 If the technology type is an internal electronic RFID animal identification technology, then the accompanying visual identifier shall be applied to the right ear and the reference animal identification applied to the left.

NOTE 3 to TABLE B-2 If the technology type is a non-electronic physical identification, then, unless otherwise specified by compliance requirements, the trial animal identification technology shall be placed to ensure that in each flock there are an equal number of animals with the technology in either ear.

Following application, the Field Trial Supervisor shall record on the Field Trial Application Report details of:

a) the procedure;

b) the identity of any animals, along with a description of any animal identification technology or applicator-related problems that were encountered;

c) a description of any animal welfare or human safety problems that were encountered;

d) any application failures along with samples of the animal identification technology which failed for provision to the Program Administrator with the Field Trial Supervisor's Field Trial Application Report.

Assessment of retention and durability (deterioration of print and materials)

At every assessment, the Field Trial Supervisor shall:

a) check the application site on each animal to ensure no adverse impact on the welfare of the animal (e.g. signs of infection, ripping etc);

b) check for the secure presence of undamaged trial animal identification technology on each animal;

c) check for evidence of print and materials deterioration or fading on:

   i. for electronic animal identification technologies using low frequency RFID: 5% of trial animals (with a minimum of 30 animals on smaller properties); and

   ii. for non-electronic animal identification technologies using physical identification: all trial animals;

d) remove any animal identification technology showing signs of structural failure, damage or adverse impacts on animal welfare and:

i. send the damaged animal identification technology to the Program Administrator with the Field Trial Assessment Report; and

NOTE The Program Administrator may conduct additional testing on the animal identification technology as required.

e) take high resolution photographs of a sample of animals with the trial animal identification technologies attached that are representative of those on the trial animals and include such photographs with the Field Trial Assessment Report.

If there is cause for concern relating to durability (i.e. physical deterioration), the Field Trial Supervisor may assess a higher number of trial animals sufficient to provide an accurate assessment of the scope of the problem.

At the 36-month assessment, the Field Trial Supervisor shall check that printing on the animal identification technology attached to live animals is visually readable at a distance of 75cm under daylight conditions and with a clean appearance to the technology.

If any animals included in the field trial have lost the trial animal identification technology, the reference identification shall be used to identify those animals. The Field Trial Supervisor shall record the occurrence of lost, damaged or deteriorated animal identification technology in their Field Trial Assessment Report.

Electronic readability

For electronic animal identification technologies using low frequency RFID, at every assessment, the Field Trial Supervisor shall ensure that:

a) each animal identification technology on a trial animal is accurately and reliably machine-read:

i. in a walk-through situation;

ii. based on at least one assessment conducted using a panel reader; and

iii. in a manner which allows each animal to move freely past a reading point in single file;

b) where any animal identification technology does not machine-read on the first attempt:

i. a second attempt shall be made to machine-read the technology following the process identified in a) i., ii. and iii; and

ii. the necessity to undertake a second machine-reading shall be noted in the Field Trial Assessment Report, including:

1) the total number of animals subject to a second machine-reading; and

2) the individual numbers of the animal identification technologies subject to a second machine-reading; and

c) where any animal identification technology does not machine-read on the second attempt:

i. the nonreading technology shall be correlated with the reference animal identification method;

ii. the occurrence of the nonreading technology shall be recorded in the Field Trial Assessment Report; and

iii. nonreading technology shall be removed without damaging the primary component; and sent to the Program Administrator with the Field Trial Assessment Report.

NOTE The Program Administrator may conduct additional testing on nonreading animal identification technologies.

Visual readability

For non-electronic animal identification technologies using physical identification, at every assessment, the Field Trial Supervisor shall:

a) ensure that each animal identification technology unit is read visually;

b) record the details of each animal identification technology unit including if it has been lost, damaged or is unreadable; and

c) rate each animal identification technology unit in terms of its readable using a scale between 1 (Poor) and 5 (Excellent).

B.8 Evaluation of Field Trial results

As part of the decision process specified in section 4.12, the Program Administrator shall provide the field trial results to the Standards Committee for evaluation and determination.

Basis for evaluation:

In evaluating field trial results, the Standards Committee shall consider the Approval Requirements and also take into consideration the following:

a) Application

i. animal identification technologies shall not exceed the application failure rate specified in the *NLIS Animal Identification Technology Requirements*.

b) Retention and readability thresholds

i. using the upper 95% confidence interval:

1) the mean loss rate in an infinite number of animals shall not exceed 3.5% at 36 months; and

2) for electronic animal identification technologies using low frequency RFID, the mean loss rate includes a maximum loss rate due to non-reading animal identification technologies of 0.5% or less over 36 months.

NOTE 1 A mean loss rate with an upper 95% confidence interval (as calculated above) not exceeding 1.5% at 6 months, 2.0% at 12 months and 3.0% at 24 months may be considered by the Standards Committee as evidence that the device is likely to meet the retention requirements of the Standard at 36 months.

NOTE 2 Animal identification technologies that do not meet the retention specifications in the first six months of the field trial may still meet the specification at 36 months if the rate of loss declines over the duration of the trial.

ii. In determining loss rates for electronic animal identification technologies using low frequency RFID:

1) the loss rate for non-reading animal identification technologies and the loss rate for those that have been physically lost (shall be calculated separately);

2) a mean loss rate shall be calculated which combines non-reading animal identification technologies with those which have been physically lost. Confounding factors that may have increased loss rates may be taken into account.

NOTE 1 A qualified biometrician may be used to calculate the loss rates, taking into account the actual numbers of animals and losses over duration of the trial at the upper 95% confidence interval using a one tail methodology. This analysis takes into account that not all animals identified at the commencement of the trial will be presented for every read and also takes into account the timing of the recorded loss.

NOTE 2 The one tail methodology is based on the Kaplan – Meier estimate of the survival function as specified in D. Collett (1994), “Modeling Survival Data in Medical Research”, Chapman & Hall, London, as applied using GenStat (VSN International Ltd. Oxford) analysis software.

NOTE 3 This methodology may be modified at the discretion of the Program Administrator on the advice of the Standards Committee.

c) Durability (i.e. physical deterioration of print and materials) thresholds

i. the number of animal identification technologies used for the duration of the field trial which were able to be visually read from a distance of 75cm under daylight conditions shall be 95% with no evidence of deterioration of the materials.

d) Animal welfare impacts

i. no adverse animal welfare outcomes as a direct result of the animal identification technology.