

NLIS Animal Identification Technology Approval Program Fundamentals and Vocabulary

Integrity Systems Company Limited (ISC)
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FORWARD

NLIS is Australia's system for the identification and traceability of foot-and-mouth disease (FMD) susceptible species including cattle, sheep and goats. NLIS was introduced in 1999 to enhance Australia's ability to trace cattle during disease and food incidents but was expanded to also include sheep and goats in 2006. NLIS reflects Australia's commitment to biosecurity and food safety and provides a competitive advantage in global markets.

Under NLIS, livestock are identified with animal identification technologies. Movements of livestock from property of birth through to slaughter are required to be recorded on the NLIS database thereby ensuring lifetime traceability for the purposes of biosecurity, food safety and market access.

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

DOCUMENT CONTROL

The latest version of all normative documents can be downloaded from Integrity Systems Company Ltd website: <https://www.integritysystems.com.au/>

Language

Original documents are in English.

Changes to documents

Normative documents are identified with a unique document code, a version number and date.

The date in the version name indicates the date the document becomes operative.

The updates will be sent to all Applicants, Suppliers, as official communication.

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INTRODUCTION

Under the Red Meat Industry Memorandum of Understanding (MOU), SAFEMEAT is established as an industry-government working partnership to provide leadership, policy advice and strategic direction for the industry to achieve the highest standards of safety, hygiene and integrity from the farm to the consumer for meat-based human food products.

The purpose and scope of SAFEMEAT is to ensure the integrity and safety of food products from meat producing livestock in order to protect Australia's market access and fulfil its Role under the MOU.

SAFEMEAT is the custodian of the rules and standards relating to the operation of the National Livestock Identification System (NLIS) and reports to the Agriculture Ministers Forum (AGMIN) through the National Biosecurity Committee.

NLIS is Australia's system for the identification and traceability of foot-and-mouth disease (FMD) susceptible species including cattle, sheep and goats. NLIS was introduced in 1999 to enhance Australia's ability to trace cattle during disease and food incidents but was expanded to also include sheep and goats in 2006. NLIS reflects Australia's commitment to biosecurity and food safety and provides a competitive advantage in global markets.

Importantly, NLIS is Australia's 'regulatory enabler', informing and guiding state and territory-based livestock identification and traceability legislation. NLIS provides industry, in partnership with government, the tools necessary to trace livestock and ensure compliance with the National Livestock Traceability Performance Standards (NLTPS) which were endorsed by the Primary Industries Ministerial Council (PIMC) in May 2004.

The Integrity Systems Company Limited (ISC)¹ is a wholly owned subsidiary of Meat & Livestock Australia (MLA). It is responsible for the delivery and administration of a number of meat and livestock industry assurance services, including the:

- Livestock Production Assurance (LPA) program; and
- National Vendor Declarations (NVDs).

Under NLIS, livestock are identified with 'devices' (i.e. animal identification technologies). Movements of livestock from property of birth through to slaughter are required to be recorded on the NLIS database thereby ensuring lifetime traceability for the purposes of biosecurity, food safety and market access.

Animal identification technologies for use under NLIS are required to be **approved** under the *NLIS Animal Identification Technology Approval Program* (the 'Program'). Initial approval is for a five-year cycle and is based on consideration of:

¹ Previously named National Livestock Identification System Limited.

- an initial assessment of samples and written application;
- field trials, typically conducted over 36 months;
- an audit of production and supply procedures;
- technology testing;
- a licence agreement; and
- ongoing monitoring of commercial sales.

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.

As custodian of the NLIS standards and rules, SAFEMEAT is also the Owner of the Program. ISC is the Program Administrator and is responsible for:

- a) developing and reviewing the Program Rules and recommending their approval to SAFEMEAT;
- b) in conjunction with the Standards Committee, maintaining oversight and periodically reviewing and recommending changes to Approval Requirements; and
- c) overseeing the approval process and administering and operating the Program in accordance with the Program Rules in an impartial and objective manner.

The Standards Committee is a technical committee appointed by SAFEMEAT that reports to the Program Administrator and is responsible for:

- a) in conjunction with the Program Administrator, developing performance criteria and requirements for animal identification technologies and recommending such to SAFEMEAT;
- b) assessing animal identification technologies against the Approval Requirements; and
- c) making recommendations for approval, or otherwise, to the Program Administrator who will then grant approval, or otherwise.

After six months of a field trial, 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.

In 2018 the approval process for animal identification technologies for use in the Australian market under NLIS was reviewed and benchmarked internationally². The review showed the approval process was robust and generally fit for purpose, however some improvements were recommended to:

- allow for consistent consideration of emerging animal identification technologies;
- ensure requirements for animal identification technologies were outcome/performance-based whenever possible to allow for maximum innovation, and not being overly prescriptive unless there was a rational reason for doing so;
- take into account state and territory regulations and requirements and the primary purpose of NLIS in relation to biosecurity, food safety and market access;
- address opportunities for improvement in the conduct of field trials; and
- to ensure effective post-market assurance of animal identification technologies after approval had been granted.

Animal identification technologies include any technology used to identify livestock. This could include, but is not limited to, all livestock tags, devices, identifiers, buttons and 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).

Approved animal identification technology consists of:

- 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.

² Schuster A and Drake G (2018). *Review of the NLIS Device Accreditation Standards and Field Trial Protocols, Final Report*. Integrity Systems Company Ltd. November.

One of the recommendations of the review was to consolidate, review and update the existing NLIS animal identification technology requirements documents³ and to restructure these into two principle sets of requirements. This reflects contemporary national and international expectations for the structure of approval programs and standards⁴. The two primary documents which form the Approval Requirements are the:

- a) *NLIS Animal Identification Technology Approval Program Rules* (the ‘Program Rules’); and
- b) *Requirements for NLIS Animal Identification Technology* (the ‘Standard’).

The Program Rules contain all the requirements for the **approval process** used by the Standards Committee and Program Administrator 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 approval 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.

The Standard contains all the outcome, performance-based and prescriptive **requirements for animal identification technologies**. It is the responsibility of the Supplier to demonstrate that their technology fulfils these requirements and, if appropriate, approved by the Program Administrator under the Program.

There are several levels of approval under the Program which are designed to facilitate the trialling of a technology and its commercial supply when certain performance criteria are met. The approval levels are:

a) Experimental approval:

May be granted in order to authorise the conduct of field trials using a limited number of technology units. Experimental approval is subject to ongoing conformity with the Approval Requirements and any additional trial conditions that may be applied.

b) Conditional approval:

May be granted after six months of a three-year field trial and authorises the commercial supply of that technology while that technology continues to be assessed for full approval against the Approval Requirements. Commercial supply is subject to the Supplier also securing state or territory government approval separately to this Program’s approval process and demonstrating ongoing conformity with the Approval Requirements.

³ NLIS Standard - Radio-Frequency Identification Devices (2018), NLIS Field Trial Protocol - Radio-Frequency Identification Devices (2016), NLIS Standard for visual tags (2017) and NLIS Protocol for device trials - Visual tags (2017).

⁴ Standards Australia’s [Rules for the Structure and Drafting of Australian Standards® \(SG-006\)](#) (2018) and the International Organization for Standardization’s (ISO) guidance documents [Conformity assessment for standards writers - Do’s and don’ts](#) (2016) and [How to develop scheme documents](#) (2019).

c) Full approval:

May be granted initially when a technology has demonstrated fulfilment of the Approval Requirements through, where required, the three-year field trial and commercial sales. Full approval is subject to ongoing conformity with the Approval Requirements throughout and beyond the validity period.

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.

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

This document contains the principles, terms and definitions that underpin and are referred to in the Approval Requirements.

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

- a) *NLIS Animal Identification Technology Approval Program Rules* (the 'Program Rules'); and
- b) *Requirements for NLIS Animal Identification Technology* (the 'Standard').

2 NORMATIVE REFERENCES

The following shall be considered normative references under the *NLIS Animal Identification Technology Approval Program*. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 1) *NLIS Animal Identification Technology Approval Program Rules*
- 2) *Requirements for NLIS Animal Identification Technology*
- 3) *ISO 9001:2015 Quality management systems – Requirements*
- 4) *ISO 31000:2018 Risk management – Guidelines*
- 5) *IEC 31010:2009 Risk management – Risk assessment techniques*
- 6) *ISO 10002:2018 Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*
- 7) *AS5018-2001 Electronic animal identification - National coding scheme*

NOTE Modified for application in Australia from ISO 11784:1996 *Radio frequency identification of animals – Code structure*

- 8) *AS5019-2001 Electronic animal identification - Radiofrequency methods*

NOTE Modified for application in Australia from ISO 11785:1996 *Radio frequency identification of animals – Technical concept*

3 TERMS AND DEFINITIONS

In accordance with the ISO/IEC Directives, Part 2, the following verbal forms of expression are used under the *NLIS Animal Identification Technology Approval Program*:

- ‘shall’ indicates a requirement;
- ‘should’ indicates a recommendation;
- ‘may’ indicates a permission;
- ‘can’ indicates a possibility or a capability.

In addition to the following terms and definitions which apply, terms which appear bold in specific sections of the Approval Requirements hold a particular meaning within that section of that document.

2.1	Animal identification technology	Any technology used to identify animals or livestock. NOTE This could include, but is not limited to, all livestock tags, devices, identifiers, buttons and 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).
2.2	Appeal	A documented objection to an Approval Decision of the Program Administrator.
2.3	Applicant	A person, cooperative, association or company that manufactures an animal identification technology which has applied for its animal identification technology to be approved in accordance with the Program Rules and has signed the Approval Agreement and Declaration, up to the point of the initial Approval Decision.
2.4	Application Form	A documented form (in electronic or hard copy format) specified from time-to-time by the Program Administrator listing all the information and associated documentation that must be completed and submitted by the Applicant.
2.5	Approval Agreement	Legally enforceable agreement between the Supplier of the NLIS Approved Animal Identification Technology and the Program Administrator. Includes the NLIS Logo License.
2.6	Approval Requirements	The set of specified requirements set by the Program Administrator and revised from time-to-time, including these Program Rules, Standard and the Approval Agreement along with any policies, instructions or procedures issued by the Program Administrator.

2.7	Approved Auditor	A person who has been approved by the Program Administrator to undertake evaluation activities in accordance with the Program Rules.
2.8	Australian advertising standards	Any standards, requirements, codes or guidelines which govern advertising. NOTE These may include the Australian Association of National Advertisers (AANA) codes and guidelines.
2.9	Authorised Representative	A person that is nominated by each party to the Program Rules that is their formal contact point, and whose up-to-date contact details are provided to the Program Administrator.
2.10	Brand	The three-character brand allocated by the Western Australia authority to identify a specific property (see also PIC).
2.11	Breeder technology	A specific animal identification technology for application to livestock that are still on their property of birth.
2.12	Cattle	Refers to Cattle, Buffalo and Bison.
2.13	Competent laboratory	A laboratory that is accredited by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) as fulfilling the requirements of ISO/IEC 17025 with an accreditation scope relevant to the testing being undertaken. NOTE The relevant ILAC MRA signatory in Australia is the National Association of Testing Authorities (NATA).
2.14	Compliance requirements	Relevant state and territory regulatory requirements or industry conformance requirements relating to, for example: <ul style="list-style-type: none"> – the supply and use of animal identification technologies as part of NLIS; – human work health and safety; – food safety; – biosecurity – animal welfare and cruelty; or – advertising.
2.15	Conditional approval (status)	The status given to an animal identification technology and authorises the commercial supply of that technology while that technology continues to be assessed for full approval against the Approval Requirements. Commercial supply is subject to the Supplier securing state or territory government approval separately to this approval process and demonstrating ongoing conformity with the Approval Requirements. NOTE 1 Conditional approval is typically awarded after demonstrating conformity with the Approval Requirements during the first six months of a 36-month field trial.

NOTE 2 Conditional approval awarded under this Program does not denote approval in the relevant state or territory jurisdictions.

2.16	Correction	Action to eliminate a detected nonconformity.
2.17	Corrective action	Action to eliminate the cause of a nonconformity and prevent reoccurrence.
2.18	Defective product	Any NLIS Approved Animal Identification Technology which has been made commercially available and which fails to meet the Approval Requirements.
2.19	Experimental approval (status)	The status given to an animal identification technology which authorises the conduct of field trials or other assessments using a limited number of technology units that are not permitted to be made available commercially. Experimental approval is subject to ongoing conformity with the Approval Requirements.
2.20	Field trial	The process of assessing new animal identification technologies against the Approval Requirements in an on-farm setting.
2.21	Field Trial Participant	A person who is responsible for the management of livestock, including traceability practices, on a Field Trial Property.
2.22	Field Trial Property	A property approved by the Program Administrator which can be a site for trials of animal identification technology.
2.23	Field Trial Supervisors	A person who has been approved by the Program Administrator to oversee field trials of animal identification technology in accordance with the Program Rules.
2.24	Full approval (status)	<p>The status given to an animal identification technology when that technology has demonstrated fulfilment of the Approval Requirements. Full approval is subject to ongoing conformity with the Approval Requirements throughout and beyond the validity period.</p> <p>NOTE 1 Full approval for new animal identification technologies is typically awarded after demonstrating conformity with the Approval Requirements during a 36-month field trial.</p> <p>NOTE 2 Full approval awarded under this Program does not denote approval in the relevant state or territory jurisdictions.</p>
2.25	ICAR	International Committee for Animal Recording.
2.26	Internal (animal identification technology)	An animal identification technology which is inside the body of livestock e.g. a Rumen Bolus or an Implant.

2.27	ISC	Integrity Systems Company Limited (ACN 134 745 038, ABN 34 134 745 038).
2.28	ISO	International Organization for Standardization.
2.29	Lifetime	Considered to be from when the animal identification technology is originally applied to the animal on its property of birth until that animal's death or it is exported as a live animal from Australia.
2.30	Lifetime traceability	The ability to track an animal's movement over its lifetime forwards and backwards through the supply chain and identify the PIC of residence of that animal at any point until its death or it is exported as a live animal from Australia.
2.31	Livestock	Cattle, sheep and goats (including fibre, meat and dairy livestock) kept either for production purposes, lifestyle reasons or as pets.
2.32	NLIS	National Livestock Identification System. Australia's system for tracking foot-and-mouth disease (FMD) susceptible species for biosecurity, food safety and market access purposes.
2.33	NLIS database	The database used to administer and manage NLIS.
2.34	NLIS Animal Identification Technology Approval Program	A conformity assessment Program for approving animal identification technologies that demonstrate ongoing fulfilment of Approval Requirements. The NLIS Animal Identification Technology Approval Program may be stated by the short form of 'Program'.
2.35	NLIS Animal Identification Technology Approval Program Rules	The ongoing rules for the administration and operation of the NLIS Animal Identification Technology Approval Program (i.e. this document). The NLIS Animal Identification Technology Approval Program Rules may be stated by the short form of 'Program Rules'.
2.36	NLIS Animal Identification Technology Requirements	The ongoing mandatory specifications and requirements for NLIS Approved Animal Identification Technology. The NLIS Animal Identification Technology Requirements may be referred to as the 'Standard'.
2.37	NLIS Approved Animal Identification Technology	An animal identification technology that is currently approved under the NLIS Animal Identification Technology Program. NLIS Approved Animal Identification Technology may be stated by the short form of 'NLIS Approved' or 'NLIS Approved Technology'.
2.38	NLIS Logo	The logo used to identify NLIS Approved Animal Identification Technologies.
2.39	NLIS Logo Licence	An agreement between the Approved Supplier and the Program Administrator which allows the Approved Supplier, as an NLIS Logo

		Licensee, to reproduce the NLIS Logo on their NLIS Approved Animal Identification Technology. Forms part of the Approval Agreement.
2.40	NLIS Logo Licensee	The entity holding the NLIS Logo Licence, and therefore the Approval Agreement with the Program Administrator.
2.41	Nonconformity	Nonfulfillment of a requirement.
2.42	PIC	Property Identification Code. An eight-character code assigned by a state or territory government authority covering a parcel of land within the one locality, operating as part of a livestock enterprise. See also Brand.
2.43	Post-breeder technology	A specific animal identification technology for application to livestock which: <ul style="list-style-type: none"> a) are no longer on their property of birth and are not already identified with breeder or post-breeder technology; or b) require additional identification using a post-breeder technology.
2.44	Producer	A person, organisation or business engaged in breeding, feeding or raising livestock. It includes feedlot operators, depot managers and persons keeping livestock for commercial production purposes, for lifestyle reasons or as pets.
2.45	Property	A parcel of land typically identified by a PIC.
2.46	Reader (hand-held or fixed)	Equipment which receives a signal from the animal identification technology containing a unique number. The signal is received by the reader and the number decoded.
2.47	Recycle	The process of collecting, recovering, disinfecting and breaking down used components in animal identification technologies before turning them into raw materials which can be used again in different animal identification technologies.
2.48	Reuse	The process of collecting, recovering, accounting for and disinfecting used components (separately or as a whole) in animal identification technologies and reissuing them for the same purpose.
2.49	RFID	Radio Frequency Identification.
2.50	Rumen capsule or bolus	A technology administered orally into ruminant species which is designed to remain permanently in the animal's rumen or reticulum.
2.51	SAFEMEAT	The national committee of red meat industry, state, territory and Commonwealth leaders which provides leadership, policy advice and strategic direction for the industry to achieve the highest standards

		of safety, hygiene and integrity from the farm to the consumer for red meat-based human food products.
2.52	Primary purpose (of the animal identification technology)	To facilitate lifetime traceability of an animal or group of animals under NLIS.
2.53	Program Administrator	ISC - Integrity Systems Company Limited (ACN 134 745 038, ABN 34 134 745 038) or its appointed agent.
2.54	Program Directory	A public directory that is maintained by the Program Administrator that lists NLIS Approved Animal Identification Technologies and their Applicant or Suppliers and provides information regarding the current status of each approval.
2.55	Program Owner	SAFEMEAT.
2.56	Product field code	The code which identifies the NLIS Approved Technology and its scope of approval on the NLIS database. The product field code is allocated to the technology by the Program Owner as part of the application process and represents the last six digits which are included in the Suppliers NLIS database upload.
2.57	Scope of Approval	Reference to the following elements in the Approval Agreement: <ul style="list-style-type: none"> d) the specific animal identification technology: <ul style="list-style-type: none"> i. including all components of any physical unit, application system or tool, instructions and packaging; ii. without any subsequent substitution or change to any components; and iii. with options for use as breeder and post-breeder technology; e) all Australian-based sites of the Supplier where the NLIS Approved Animal Identification Technology is produced; f) the species which the animal identification technology is approved for use with; g) the product field code the Supplier intends to use as the unique reference for that specific technology; h) how the animal identification technology is applied to an animal;

i) *the NLIS Animal Identification Technology Approval Program*; and

j) the Approval Requirements.

2.58	Standards Committee	The Committee constituted by SAFEMEAT responsible for oversight of the Standard.
2.59	Supplier	A person, cooperative, association or company that manufactures an animal identification technology or reader which has been granted approval by the Program Administrator in accordance with the Approval Requirements.
2.60	Suspended	The loss of approval for a specified time.
2.61	Suspended (status)	The status given to NLIS Approved Technology that has had approval suspended.
2.62	Technology	A means of identifying an animal or a group of animals. NOTE This is not a platform or a system, it is the means to identify an animal or groups animals.
2.63	Transponder	An integrated circuit (e.g. microchip) that has the capacity to respond to an electronic signal at the appropriate frequency from a reader and once activated, respond with a signal containing the encoded unique number that can be decoded by the reader.
2.64	Validity period	The period of time in which an Approval Agreement is current and valid.
2.65	Vendor	A person, organisation or company selling livestock.
2.66	Visual identifier	A means of visually identifying animals externally which have internal animal identification technologies. NOTE Such visual identifiers are commonly attached to an animal's ear.
2.67	Withdrawn	The permanent loss of approval.
2.68	Withdrawn – (status)	The status given to NLIS Approved Technology that has had approval withdrawn.
2.69	Withdrawn – Voluntary (status)	The status given to NLIS Approved Technology where the Supplier has voluntarily withdrawn approval of that NLIS Approved Technology.
2.70	Year of birth colour system	A visual system that rotates through a defined sequence of colours used on a voluntary basis to denote the year of birth of the animal.

