

**Ministry of Agriculture and Forestry
P O Box 2526, Wellington, New Zealand**

MAF Food: Dairy & Plants

Circular no. 56

Dairy Industry Regulations 1990

***Performance Measurement of Dairy
Laboratories (D303.1)***

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Issue of Circular

Regulation 59 of the *Dairy Industry Regulations 1990* allows the Director-General of the Ministry of Agriculture and Forestry to issue Circulars setting out criteria for matters which must be approved by, or done to the satisfaction of, the Director-General, pursuant to the *Dairy Industry Regulations 1990*.

This Circular, no. 56, containing 'MAF Standard D303.1, "Performance Measurement of Dairy Laboratories,"' is issued in accordance with that regulation 59.

This Circular, no. 56, takes effect on 11 May 2000.



Tim Knox
Director, Dairy and Plant Products
MAF Food Assurance Authority

11 May 2000

(Signed under authority delegated by the Director-General of MAF, pursuant to regulation 59 of the Dairy Industry Regulations 1990.)

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1 Background

The MAF Standard for Performance Measurement of Dairy Laboratories was developed to:

- outline the requirements for linking the assessment of laboratories to their performance in complying with regulatory requirements, and
- describe the acceptable criteria (means for satisfying MAF that the requirements have been achieved).

2 Summary

This Standard specifies requirements linking the level of assessment of dairy laboratories to their demonstrated compliance with the requirements of the *Dairy Industry Regulations 1990*.

Appendix One outlines acceptable criteria for demonstrating that the outcomes in the Standard are achieved, including:

- Laboratories are assigned to one of three categories: Reduced, Standard/Entry, or Increased Assessment.
- The assessment category determines the frequency and intensity of accreditation/recognition body assessment of the laboratory.
- Laboratories commence in the Standard/Entry Assessment category unless there is a risk to food safety. In these cases, MAF Food: Dairy & Plants assigns laboratories to the Increased Assessment category.
- MAF Food: Dairy & Plants reviews the category to which a laboratory is assigned when receiving a recommendation from MAF Compliance and the accreditation/recognition body, a report of a critical non-compliance or change in accreditation/recognition status, or a request for a review from a laboratory or another party.
- Moving to a category with a decreased level of assessment requires the laboratory to demonstrate compliance appropriate to the new category.

Proposals for alternative criteria may be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved.

3 Outcome

The performance of registered dairy laboratories is assessed by MAF and their accreditation/recognition bodies in accordance with regulation 56 of the *Dairy Industry Regulations 1990*, at a frequency and intensity based on their demonstrated compliance with regulations 25 to 35 of the *Dairy Industry Regulations 1990*.

4 Effective changes

This Standard will introduce the following changes to the previously existing situation:

- For laboratories who remain in the existing regulatory system, there will be no changes.
- For laboratories who move to the ORM system, performance based assessment will be introduced. This will result in the following changes:
 - MAF Compliance will no longer routinely visit laboratories to assess them.
 - The frequency of assessment by the accreditation/recognition body will be based on the body's assessment of the laboratory's performance against MAF requirements, and MAF Compliance's assessment of the laboratory's performance related to reporting.
 - When laboratories demonstrate regulatory compliance, there is the opportunity for reducing the frequency and intensity of assessment. Laboratories which fail to meet regulatory requirements or have inadequate systems will be assessed by the accreditation/recognition body at an increased frequency.

5 Implementation

This Standard will apply from the date of its notification by Circular. It will apply to those dairy laboratories who have moved to the ORM system.

6 Effect on compliance costs

Compliance costs may be reduced for some laboratories, as a result of the cessation of routine MAF Compliance audits.

Assessment frequency will have a significant financial impact for laboratories. Laboratories classified in the reduced frequency category for compliance will have fewer full assessments by the accreditation/recognition body, resulting in reduced costs.

Laboratories classified in the increased frequency category will have increased scrutiny and assessment. Laboratories in this category will consequently incur increased costs due to increased use of the services of accreditation/recognition bodies.

MAF Standard D303.1, "Performance Measurement of Dairy Laboratories"

1.0 SCOPE

This Standard contains the outcomes for the performance-based assessment of dairy laboratories by MAF. All registered dairy laboratories operating in the ORM system must comply with this Standard.

2.0 PURPOSE

This Standard sets out the outcomes that are specified in the *Dairy Industry Regulations 1990* relating to the performance-based assessment of dairy laboratories by MAF Food: Dairy & Plants.

The acceptable criteria outlined in Appendix One of this Standard were developed in consultation with industry to establish clear rules for judging to which category a dairy laboratory should be assigned, and to assist parties to achieve the outcomes described in this Standard. Proposals for alternative criteria will be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved.

3.0 OUTCOME

The performance of registered dairy laboratories is assessed by MAF and their accreditation/recognition bodies in accordance with regulation 56 of the *Dairy Industry Regulations 1990*, at a frequency and intensity based on their demonstrated compliance with regulations 25 to 35 of the *Dairy Industry Regulations 1990*.

4.0 INTERRELATED REQUIREMENTS

The following Standards must be read in conjunction with this Standard.

- MAF Standard D301, "MAF-Approved Dairy Test Methods" (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry.
- MAF Standard D302, "Registration of Dairy Laboratories." Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry.

5.0 ADDITIONAL RESOURCES

The following document is a useful resource.

- *Dairy Products Safe and True*. Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry. World Wide Web address: www.maf.govt.nz/Dairy/

6.0 DEFINITIONS

These definitions must be read in conjunction with the interpretations in the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*.

MAF Food: Dairy & Plants definitions of terms can be found in their “Glossary of Terms,” available on the Dairy & Plants website (www.maf.govt.nz/Dairy/).

Accreditation body – An internationally recognised, independent organisation which is authorised to accredit organisations to certain ISO standards. Currently, only IANZ and JAS-ANZ are accreditation bodies in New Zealand.

Assessment – Systematic examination of an individual, organisation, plan, programme, or system against regulatory requirements.

Critical non-compliance – An action, event or omission which may result in:

- failure of dairy produce to comply with regulatory requirements;
- failure to follow the lawful direction of an Inspector;
- an alleged offence against the *Dairy Industry Act 1952* or *Dairy Industry Regulations 1990*;
- a critical situation;
- failure of a critical control point within a MAF-approved programme or plan;
- failure to identify when dairy produce is non-conforming;
- failure to stop a non-compliance;
- failure to keep accurate and complete records;
- failure to provide accurate, complete, and timely reports;
- failure to dispose of non-conforming dairy produce in compliance with regulatory requirements;
- failure to prevent recurrence of a non-compliance; and/or
- failure to rectify a non-compliance within the specified timeframe.

Critical situation - Any situation which, in the professional judgement of the Inspector, places public health, animal welfare, market access, official assurances, national good, or MAF’s credibility at risk, or where an offence is suspected.

Dairy produce – Milk, cream, butter, cheese, and any other product of milk or cream.

Dairy product – Dairy produce intended for sale in, or export from, New Zealand for human consumption; and

- (a) includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream; but
- (b) does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

Full assessment – an assessment to confirm that staff, facilities, operations and procedures comply with regulatory standards and documented procedures are followed. Information gathered will include, but need not be limited to, records, discussions with management and personnel, and the observation of activities.

IANZ – International Accreditation New Zealand. An accreditation body.

ISO Guide 25 – ISO/IEC Guide 25: 1990 (E) entitled “General requirements for the technical competence of testing laboratories” (to be replaced by ISO Standard 17025).

ISO Standard 17025 – ISO Standard entitled, “General requirements for the competence of testing and calibration laboratories” (will replace ISO Guide 25:1990).

JAS-ANZ – Joint Accreditation System of Australia New Zealand. An accreditation body.

MAF Compliance – The Compliance and Investigation Group of MAF Food, reporting to the Director, Compliance and Investigation Group.

MAF Food – The Food Assurance Authority of the Ministry of Agriculture and Forestry.

MAF Food: Dairy & Plants – The Dairy and Plant Products Group of MAF Food, reporting to the Director, Dairy and Plant Products.

MAF Compliance - The Compliance and Investigation Group of MAF Food, reporting to the Director, Compliance and Investigation Group.

Non-compliance – Any failure to comply with regulatory requirements.

Non-conforming – In relation to dairy produce, any that is suspected or known not to meet regulatory requirements.

Recognition body – An organisation approved by MAF to recognise Category 2 dairy laboratories.

Safe – In relation to any dairy product, “safe” means satisfactory, fit for human consumption, and not having in it or on it any pathogenic organisms

- (a) that are present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; or
- (b) that
 - (i) are not present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; but
 - (ii) by virtue of their ability to reproduce, to produce toxins, or both, make the product potentially harmful or injurious to the health of the people who may eat or drink it.

In relation to any dairy produce that is not a dairy product, “safe” means satisfactory, and fit for the manufacture of dairy products.

Sanction – Official response to regulatory non-compliance.

Significant change – Any change made to key staff, environment, premises, equipment, facilities, process or product which may affect food safety.

Surveillance assessment – an assessment of practical implementation of documented procedures to determine the conformance of that practice with the accreditation criteria and documented procedures.

7.0 REQUIREMENTS

The performance of all MAF-registered dairy laboratories must be assessed by their accreditation/recognition body and MAF Compliance at the frequency specified by MAF Food: Dairy & Plants.

The following performance standards must be assessed:

- for Category 1 laboratories, the history of compliance with ISO Standard 17025 and MAF Food: Dairy & Plants requirements,
- for Category 2 laboratories, the history of compliance with MAF Standard MRD-Stan 5 and other MAF Food: Dairy & Plants requirements,
- performance, as indicated by the regular and exception reports sent to MAF Compliance, and
- management and resolution of non-compliances identified in the regular and exception reports.

8.0 VERIFICATION

Verification of compliance with this Standard is undertaken by the accreditation/recognition body during the routine assessments of the laboratory, and by MAF Compliance. The frequency and intensity of assessment is defined by MAF, based on the performance assessment category to which the laboratory to which they are assigned and their performance.

8.1 Criteria

The criterion for assessing compliance with this Standard is as follows:

- the laboratory's performance complies with the requirements of the performance assessment category to which it has been assigned.

8.2 Decision

The party is non-compliant if the criterion for assessing compliance is not met.

8.3 Result

8.3.1 Compliant laboratories

The frequency of performance assessment of compliant laboratories will remain the same, or will be reduced if the laboratory meets the requirements of a reduced frequency category.

8.3.2 Non-compliant laboratories

The frequency of performance assessment of non-compliant laboratories will be increased.

Where the laboratory consistently fails to meet requirements, the Director-General may:

- impose new conditions or vary the conditions of registration, or
- withdraw registration of the laboratory.

MAF Food will not accept laboratory reports or test results from laboratories whose registration has been withdrawn.

Where a laboratory is suspected of committing an offence under the *Dairy Industry Act 1952* or the *Dairy Industry Regulations 1990*, MAF Enforcement Unit may investigate the laboratory and prosecution may follow.

9.0 VERSION CONTROL

Version	Date	Status	By
303.1	11 May 2000	Promulgated by Circular no. 56	Director, Dairy and Plant Products

This copy may not be the most recent version of this document. It was current at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the Dairy and Plant Products Group of MAF Food or check its website (www.maf.govt.nz/Dairy) to confirm that this is the current version.

Appendix One

ACCEPTABLE CRITERIA

The following are criteria by which a dairy laboratory operating in the ORM system may be judged to achieve satisfactorily the requirements of section 7 of this Standard. Those dairy laboratories will be assigned by MAF to a performance assessment category according to the following criteria.

Proposals for alternative criteria will be accepted by MAF, providing it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved. A guide to the information required for these proposals and the procedures used by MAF to assess proposals can be obtained from MAF Food.

1.0 CLASSIFICATION

Each laboratory operating under ORM is assigned to one of the following performance assessment categories based on their demonstrated compliance regulatory requirements:

- Reduced Assessment,
- Standard/Entry Assessment, or
- Increased Assessment.

1.1 Reduced Assessment category

To be assigned to, and remain in, the Reduced Assessment category, the laboratory meets all the criteria for the Reduced Assessment category in Table A1.1. The laboratory has demonstrated compliance with the criteria for at least two seasons.

1.2 Standard/Entry Assessment category

To be assigned to, and remain in, the Standard/Entry Assessment category, the laboratory meets all of the criteria for the Standard/Entry Assessment category in Table A1.1. The laboratory has demonstrated compliance with the criteria for at least one season.

1.3 Increased Assessment category

A laboratory which:

- fails to meet ISO Standard 17025 or MRD-Stan 5 (whichever is relevant) or MAF Food: Dairy & Plants requirements, or
- has critical non-compliances in reporting to MAF Compliance, or
- has critical non-compliances in management and resolution of its own non-compliances,

will be assigned to the Increased Assessment category.

2.0 ENTRY CLASSIFICATION

When a laboratory is accepted into the ORM system, MAF Food: Dairy & Plants reviews the laboratory's compliance. Where a laboratory demonstrates an appropriate level of compliance, they are assigned to the Standard/Entry Assessment Category. If the laboratory fails to demonstrate compliance to one or more areas, they are assigned to the Increased Assessment Category.

MAF Food: Dairy & Plants advises the manager of the laboratory of the category to which they have been assigned and the frequency of assessments.

The manager of the laboratory implements performance-based assessment frequency as instructed by MAF Food: Dairy & Plants.

3.0 DEMONSTRATION OF COMPLIANCE

The laboratory demonstrates compliance at the level appropriate to the performance assessment category to which it has been assigned. Refer to Table A1.1 below for the criteria used to demonstrate compliance. Failure to meet any of the requirements will result in reclassification to a performance assessment category with higher levels of assessment (refer to section 5 below).

Table A1.1 *Criteria for the demonstration of compliance appropriate to each performance assessment category*

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Assessment by accreditation/ recognition body	Compliance with ISO Standard 17025 or MRD-Stan 5, and MAF requirements demonstrated for two years.	Compliance with ISO Standard 17025 or MRD-Stan 5, and MAF requirements demonstrated.	Fails to demonstrate compliance with ISO Standard 17025 or MRD-Stan 5 or MAF requirements.
Reporting	Regular and exception reports complete accurate and on time for at least two seasons.	a. Regular and exception reports complete accurate and on time for at least one season; or b. regular reports occasionally incomplete or late and exception reports are complete, accurate and on time.	a. Regular or exception reports contain incomplete information or factual errors or are persistently late; or b. exceptions are not reported.
Management of critical non-compliances	<ul style="list-style-type: none"> • Critical non-compliances identified; • full traceback completed to identify root causes; • corrective actions completed in a timely manner; • full analysis of the risk to the operation from this type of non-compliance completed; and • actions taken to eliminate the risk of potential non-compliances or monitoring systems implemented to identify potential non-compliance in the operation. 	Critical non-compliances identified and managed in accordance with MAF requirements.	a. Critical non-compliances not identified; or b. critical non-compliances are identified and inadequately managed.

4.0 ASSESSMENT REQUIREMENTS

The manager of the laboratory ensures that the assessment required for the performance assessment category to which they have been assigned are undertaken as specified.

The assessment requirements of each performance assessment category are specified in Table A1.2 below.

Table A1.2 *Assessment requirements for each performance assessment category*

Assessment	Performance Assessment Category		
	Reduced Assessment Category	Standard/Entry Assessment Category	Increased Frequency Category
Assessment by the accreditation/ recognition body	Full assessment of the laboratory is required every two years; and a surveillance assessment is required in the alternate year.	Full assessment of the laboratory is required on an annual basis	Full assessment of the laboratory is required at least every six months. The frequency is defined by MAF Food: Dairy & Plants and is dependent on the degree of non-compliance and risk. MAF Food: Dairy & Plants may increase the frequency of TPA assessment at its own discretion or on the recommendation of the accreditation/ recognition body.
Regular reporting	Quarterly	Monthly	Monthly or more frequently, as specified by MAF Food: Dairy & Plants.

5.0 RECLASSIFICATION

5.1 Initiation of a review

MAF Food: Dairy & Plants initiates a review of the category to which a laboratory is assigned on receipt of any of the following communications.

5.1.1 MAF Compliance recommendation for reclassification to a category with decreased levels of assessment

When, as a result of an assessment, the accreditation/recognition body and MAF Compliance are satisfied that the laboratory demonstrates compliance with all the criteria in Table A1.1 for the recommended reclassification category, they submit a recommendation to MAF Food: Dairy & Plants for reclassification. Recommendations for reclassification are made using the form provided in Annex A, with evidence to support the recommendation.

5.1.2 MAF Compliance recommendation for reclassification to a category with increased levels of assessment

When, as a result of an assessment, the accreditation/recognition body or MAF Compliance identifies that the laboratory fails to comply with one or more of the criteria in Table A1.1 for the category to which it is assigned. Recommendations for reclassification are made using the form provided in Annex A, with evidence to support the recommendation.

5.1.3 Notification of significant changes

A report of the occurrence of any of the following significant changes is received from the laboratory, MAF Compliance or accreditation/recognition body:

- change of ownership,
- change of laboratory management,
- change of authorised, accredited and approved signatories, or
- significant alterations to the premises or equipment.

5.1.4 Report of a critical non-compliance

A report of a critical non-compliance within the laboratory, provided in accordance with the reporting requirements specified in MAF Standard D302, “Registration of Dairy Laboratories.”

5.1.5 Request for review by the laboratory

A request by a laboratory for MAF Food: Dairy & Plants to review the category to which it is assigned. A laboratory may request a review by notifying MAF Food: Dairy & Plants in writing, setting out reasons for seeking the review. A copy of the request is sent by the laboratory to the laboratory's accreditation/recognition body.

5.1.6 Request for review by another party

A request by any party for MAF Food: Dairy & Plants to review the category to which a laboratory has been assigned. Any party may request a review by notifying MAF in writing, setting out reasons for seeking the review. Copies of the request are sent by the party to the laboratory and the laboratory's accreditation/recognition body.

5.1.7 An offence is committed

The accreditation/recognition body or MAF Compliance provides evidence that the laboratory has falsified a test report, deliberately withheld information or committed any other offence against the regulations.

5.2 Review

MAF Food: Dairy & Plants reviews the category to which a laboratory is assigned and, where appropriate, reassigns a new category.

This review will consider the criteria in Table A1.1 and all the available information, including any case that has been provided in writing. MAF Food: Dairy & Plants may, for the purposes of the review, undertake or commission an assessment of the laboratory's quality system. This assessment will be at the laboratory's expense where the laboratory has requested the review.

5.3 Outcome

MAF Food: Dairy & Plants will advise the manager of the laboratory of either:

- the category to which they have been assigned, the frequency of assessments and the date of effect; or
- confirmation of the existing category, if there is no change of classification.

The manager of the laboratory implements performance-based assessments at the frequencies instructed by MAF Food: Dairy & Plants. This includes advising and making the necessary contractual arrangements with the accreditation/recognition body.

Annex A

RECOMMENDATION FOR RECLASSIFICATION OF A DAIRY LABORATORY

Name of laboratory:

MAF registration number:

Name of contact person:

Street address:

Postal address:

Telephone number:

Fax number:

Current category: *please circle*

Reduced
Assessment

Standard/Entry
Assessment

Increased
Assessment

Date assigned to current category:

Recommended category: *please circle*

Reduced
Assessment

Standard/Entry
Assessment

Increased
Assessment

Recommended dated for reclassification:

Reclassification recommended by: _____
Name of accreditation/recognition body

Name of assessor

Reclassification supported by: _____
Signature of National Assessor, MAF Compliance

Tick the appropriate boxes in the table below:

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Assessment by accreditation/ recognition body	Compliance with ISO Standard 17025 or MRD-Stan 5, and MAF requirements demonstrated for two years.	Compliance with ISO Standard 17025 or MRD-Stan 5, and MAF requirements demonstrated.	Fails to demonstrate compliance with ISO Standard 17025 or MRD-Stan 5 or MAF requirements.
Reporting	Regular and exception reports complete accurate and on time for at least two seasons.	a. Regular and exception reports complete accurate and on time for at least one season; or b. regular reports occasionally incomplete or late and exception reports are complete, accurate and on time.	a. Regular or exception reports contain incomplete information or factual errors or are persistently late; or b. exceptions are not reported.
Management of critical non-compliances	<ul style="list-style-type: none"> • Critical non-compliances identified; • full traceback completed to identify root causes; • corrective actions completed in a timely manner; • full analysis of the risk to the operation from this type of non-compliance completed; and • actions taken to eliminate the risk of potential non-compliances or monitoring systems implemented to identify potential non-compliance in the operation. 	Critical non-compliances identified and managed in accordance with MAF requirements.	a. Critical non-compliances not identified; or b. critical non-compliances are identified and inadequately managed.