Version 6 **March 2004**

MANUFACTURING PRACTICE - SCALE AND METERING DEVICE VERIFICATION

I Proposed Regulatory Text

13. (1) All scales and metering devices used in the making of medicated feed must be appropriate for the range of weights or volumes to be measured, and must be tested for accuracy

(*a*) at the time of installation; and

(*b*) as frequently as necessary to ensure proper functioning, but not less than once a year.

(2) Every licensed operator must have written procedures for the calibration of scales and metering devices used in the making of medicated feed to ensure that their accuracy is maintained in accordance with

(*a*) the applicable in-service limits of error for those scales and metering devices set out in Divisions VI and XI of Part V of the *Weights and Measures Regulations*; or

(*b*) a performance standard listed in the most recent *Device Performance Verification List*, published by the Canadian Food Inspection Agency.

II Rationale for Regulatory Requirements

Accurate measurement of feed ingredients is a critical step in the making of medicated feeds to the target potency. Errors in measurement in the making of a particular feed would be impossible to correct elsewhere in the manufacturing process for that batch of feed. Scales and metering devices must be suitable for the range of weights or volumes to be measured, and must be calibrated and maintained properly to avoid errors in measurement of medications and other ingredients.

III Items to Consider When Developing Procedures to Meet Regulatory Objectives

A Equipment

- Manufacturing equipment - Scales and metering devices should be suitable for their intended purpose in terms of capacity, graduation, and sensitivity.

  Capacity Scales: the greatest weight that can be weighed on a given scale
  Metering devices: the maximum quantity of an ingredient that can be delivered to the mill per unit of time.

Sensitivity Scales: the smallest weight that will cause the scale indicator to move (could be weight beam, dial, load cell, etc.). For example, a scale with 100 g sensitivity can not be used to weigh 50 g.

Metering devices: the minimum difference in the quantity of an ingredient that can be delivered accurately with the device with a single increment change in dial settings. For example, a metering device that is adding an ingredient at a rate of 2 kg/tonne at it's lowest setting can not be used to add an ingredient at a rate of 1 kg/tonne.

Graduation Scales: the finest division on a scale beam, digital readout, printer.
Metering devices: the incremental dial settings that control product flow to the mill.

- Accuracy: Scales: tolerance or variance from true weight. Should be 0.1% of the **capacity of the scale** or ± 1 graduation, whichever is greater, for new scales. Scales which have been in operation should have a maintenance tolerance of 0.2%. For example, a 10 kg capacity micro scale (with .01 kg graduations) that has been in operation should not vary more than (10 kg x 0.2% = 0.02 kg) 0.02 kg from a test weight.
  Metering devices: tolerance or variance from target output. Should be 5 % of target output, or ± 1 graduation. For example, a proportioner mixer intended to mix a medicated macro premix at 2.5% of the mix should be within a range of (2.5 % x 5% = 0.125 %) 2.375 - 2.625% of the total mix.
- Testing equipment: Certified weights, second scale, flow meters, timers, rev. counter

B Written Procedures

Procedures must describe:

- the method and frequency of calibration* of all scales and meters
- the method and frequency of testing scales and meters for accuracy - to include acceptable tolerances
- the corrective actions to be taken when measuring devices are determined to be out of tolerance

IV Documentation and Records

- Documentation to support the suitability of the equipment for the intended purpose (e.g., equipment specifications).
- Records of calibration
- Records of verification** of accuracy of measuring devices. For example, test weights of certified weights, test weights of actual product as measured on a second scale, etc. (See attached appendix on scale verification from the ANAC GMP manual)
- Records of maintenance and repair
- Records of corrective actions when measuring devices are determined to be out of tolerance

V Appendices

- Sample calibration records
- Sample equipment testing records
- Checklist for Scales and Metering Devices.
- Sample written scale/metering device performance testing procedures
- Sample checklist for Scales and Metering Devices

** Calibration means to fix/adjust a scale or metering device.*
*** Verification means to test the scale or metering device for accuracy.*

APPENDIX V

Following are two examples for documentation of scale verification, one from a commercial scale company and the other from a feed manufacturer's in-house quality assurance program.

FEED SCALE CO.

Date of Service: _____

MAKE	MODEL	SER.NO.	LOCATION	CAPACITY	ADJUSTED (Y or N)
Certified Standard Applied	lb ( ) kg ( )				
Reading					
After Adjustments					
Comments:					

MONTHLY SCALE CHECK

Date: _____ Last Date Serviced: _____

	Test Weights:	20	40	60	80	100	120
Use: 20 or 25 kg bags (Specify)	Scale Reading:						
	Reading:						
add 5 bags remove wts.							
add 5 bags add wts.							
add 5 bags remove wts.							
add 5 bags add wts.							
add 5 bags remove wts.							
add 5 bags add wts.							
add 5 bags remove wts.							

PAN SCALE VERIFICATION

Test Weights	200 g	500 g	1 kg	5 kg	10 kg	20 kg
Scale Reading:						

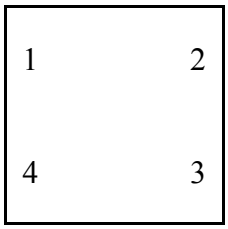
Conducted by: _____Checked by: _____

MONTHLY SCALE CHECK

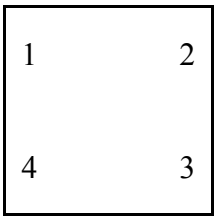
Last Date Serviced: _____

Date: _____ Done by: _____

PAN SCALE
(graduation 0.01 kg with
0.005 kg floater)



FLOOR SCALE
(graduation 0.02 kg)



POSITION	TEST WT.	SCALE READING	POSITION	TEST WT.	SCALE READING
1	100 g		1	20 kg	
2	100 g				
3	100 g		2	20 kg	
4	100 g				
1	200 g		3	20 kg	
2	200 g				
3	200 g		4	20 kg	
4	200 g				
1	500 g		1	40 kg	
2	500 g				
3	500 g		2	40 kg	
4	500 g				
1	1 kg		3	40 kg	
2	1 kg				
3	1 kg		4	40 kg	
4	1 kg				
1	5 kg		1	60 kg	
2	5 kg				
3	5 kg		2	60 kg	
4	5 kg				
1	20 kg		3	60 kg	
2	20 kg				
3	20 kg		4	60 kg	
4	20 kg				

Checklist for Scales and Metering Devices

Task 1 **Assess suitability of all scales in this area**

Rating Type **Compliance** **Regulations Respecting the Making of Medicated Feeds Section 13**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard To receive a satisfactory rating, all scales used in the manufacture of feeds must:

- □ have a capacity suitable for its intended purpose (i.e., *quantity measured must not exceed scale capacity*)
- □ have a sensitivity suitable for its intended purpose (i.e., *scale must not be used to weigh ingredient(s) in quantities lower than the sensitivity of the instrument. For example, a scale with 100 g sensitivity can not be used to weigh 50 g.)*
- □ have a graduation suitable for its intended purpose (i.e., *scale must not be used to weigh quantities more precisely than the instrument allows. For example, a scale with 1 kg graduations must not be used to weigh 1.5 kg of an ingredient.)*

Task 2 **Assess suitability of all metering devices in this area**

Rating Type **Compliance** **Regulations Respecting the Making of Medicated Feeds Section 13**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard To receive a satisfactory rating, all metering devices used in the manufacture of feeds must:

- □ have a sensitivity suitable for its intended purpose (i.e., *metering devices must not be used to add ingredient(s) in a quantity lower than it's sensitivity. For example, a metering device that is adding an ingredient at a rate of 2 kg/tonne at it's lowest setting can not be used to add an ingredient at a rate of 1 kg/tonne)*
- □ have a graduation suitable for its intended purpose (i.e., *metering devices must not be used to dispense more precisely than the instrument allows. For example, a metering device that increases inclusion of an ingredient at a rate of 2 kg/tonne per increase in graduation setting can not be used to increase inclusion at a rate of 0.5 kg/tonne)*

Task 3 **Assess adequacy of written scale and metering device verification procedures and records**

Rating Type **Compliance** **Regulations Respecting the Making of Medicated Feeds Section 13**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard **This task should be repeated for each scale or metering device used in the manufacture of medicated feed**

To receive a satisfactory rating, the establishment must have written scale and metering device verification procedures and records for each scale or metering device used in the manufacture of medicated feed which contain the following information:

Scale and Metering Device Verification Records

- the name or other information (e.g., model, serial number, location etc.) which identifies the scale/metering device to which the test record applies;
- the scale/metering device verification testing date(s);
- details regarding the procedures that were used to verify the performance of scale (including information on the number of test weights used, the sequence of addition and removal of the test weights from the scale, location where test weights were placed, etc.); or
- details regarding the procedures that were used to verify the performance of metering device accuracy (including information on the time/volume/weight of the material delivered by the metering device and a comparison of theoretical versus actual addition); and
- copies of records must be kept for a period of at least three years from the date of testing.

Scale and Metering Device Verification Procedures

- written scale and metering device verification testing procedures must stipulate that at a minimum the accuracy of scales and metering devices must be tested at the time of installation (when installed after the Regulations have come into effect), after a major repair or modification and at least once/per year thereafter.

Task 4 **Evaluate performance of scales/metering devices used in the manufacture of medicated feed in this area**

Rating Type **Compliance Regulations Respecting the Making of Medicated Feeds Section 13**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard **This task should be repeated for each scale or metering device used in the manufacture of medicated feed**

To receive a satisfactory rating, the establishment must maintain a verification record for each scale and metering device verification record must contain the following information:

- evidence that the scale is accurate (e.g., records showing that the scale can weigh given test weights within 0.2% of the capacity of the scale); and
- evidence that the metering device is accurate (e.g., records showing test batches are within 5% of the intended formulation or ± one graduation whichever is more).

Task 5 **Assess adequacy of investigations of out of tolerance scale/metering device testing results**

Rating Type **Compliance Regulations Respecting the Making of Medicated Feeds Section 13**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard To receive a satisfactory rating, the establishment must have:

- written procedures detailing follow up procedures and corrective actions to be taken when scale/metering device performance is outside of critical limits which indicate that
  - the manufacturer must stop using the scale/metering device until its' accuracy is within critical limits;
  - the manufacturer must stop selling and using all lots of animal food that are likely to be affected by the discrepancy;
  - must promptly conduct an investigation and take the necessary corrective measures; and
- the establishment must have evidence documenting that these procedures have been followed.

Scale/Metering Device Performance Testing Procedures

1. Identification of Scale/Metering Device:

These written procedures apply to the following scale/metering device:

Name:
Model:
Serial #:

2. Testing Frequency:

The accuracy of the scale/metering device shall be verified at a frequency as per the manufacturer's specifications (see operators manual) or at least once per year. In addition, the accuracy of the scale/metering device shall be verified after any major repair or modification is made.

3. Testing Procedures

Testing procedures shall be as follows:

3.1 Testing Procedure:

For Scales:

Using certified test weights, add 5 known weights to the scale (trying to approach scale maximum or at least working level). Record weight after each addition on the scale accuracy verification record. Remove the weights in reverse sequence. Record the weight as each weight is removed and when all weights have been removed on the scale accuracy verification record.

Load scale to appropriate working level. Record weight. Using certified test weights, add 5 known weights to the scale (trying to approach scale maximum or at least working level). Record weight after each addition on the scale accuracy verification record. Remove the weights in reverse sequence. Record the weight as each weight is removed and when all weights have been removed on the scale accuracy verification record.

Load scale to maximum capacity. Remove weight to ensure scale returns to zero.

Critical Limit:

The scale will be deemed to be accurate if the variation from the true weight is less than 0.1% of the capacity of the scale or ± one graduation, whichever is greater, at the time of installation for new scales. Other scales will be deemed to be accurate if the variation from the true weight is less than 0.2% of the capacity of the scale.

For Metering Devices:

For a minimum of two batches, check the calibration of the metering device against the theoretical formula using the following procedures.

Run the metering device for each ingredient for a fixed period of time. Weigh each individual ingredient using a scale that has been verified for accuracy. Compare the actual weights to the theoretical weights. Record actual and theoretical weights on the metering device accuracy verification record.

Critical Limit:

The metering device will be deemed to be accurate if the variation from the true weight is within 5 % of the target output or deviation does not exceed the amount delivered by one increment change in the meter setting.

4. Follow up procedures when the accuracy of scale/metering device is not within critical limits identified above

Should the initial scale/metering device test be above the critical limit, the scale service company shall be called to service the scale/metering device. After the repairs/modifications have been made, a second test for accuracy must be performed following the procedures outlined in Section 3.

Checklist for Scales Used in the Manufacture of Medicated Feeds	
1. Identification of the Scale	**(e.g., name, location, model, serial number, etc.)**
2. Ingredients Weighed by the Scale □ Grains □ Macro Premixes □ Mineral Ingredients/Vitamins	□ Protein Ingredients/Protein Supplements □Micro Premixes □ Medicating Premixes (DIN Products)
3. Date of Scale Installation:	
4. Suitability of Capacity of the Scale (Maximum weight measured must not exceed capacity)	
Capacity of scale (from Operator Manual):	Maximum weight measured by scale:
5. Suitability of Sensitivity of the Scale (Minimum weight measured must not be less than the sensitivity)	
Sensitivity of scale (the smallest weight that will cause the scale indicator to move as determined annually by testing):	Minimum weight measured by scale:
6. Suitability of Graduation of the Scale (Weights measured must be in full graduations)	
Graduation of scale (the finest division on a scale beam, digital readout, printer)	Most precise weight measured by scale:

Checklist for Metering Devices Used in the Manufacture of Medicated Feeds	
1. Identification of the Metering Device **(e.g., name, location, model, serial number, etc.)**	
2. Ingredients Metered by Device: □ Grains □ Macro Premixes □ Mineral Ingredients/Vitamins □ Protein Ingredients/Protein Supplements □Micro Premixes □ Medicating Premixes (DIN Products)	
3. Date of Metering Devise Installation:	
4. Suitability of Sensitivity of the Metering Device (Minimum weight delivered by the metering device must not be less than the amount delivered with a single increment change in dial setting)	
Sensitivity of metering device (the smallest weight that is delivered by a single increments change in the dial setting as determined annually by testing):	Minimum weight metered by device:
5. Suitability of Graduation of the Metering Device (Amounts metered must be in full graduations)	
Graduation of metering device (the finest division on the dial, digital readout, etc.)	Most precise weight metered by device: