



The Art of Raw Materials and Supplier Qualification

West Coast Chapter, PDA

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Outline

- Supplier Qualification
- Raw Materials Qualification
- Risk assessment
 - Critical and non-critical materials
 - Triaging suppliers
- Risk management
 - Choosing sampling and testing plans
 - Audits and supplier evaluations
 - Skip lot testing



Supplier Qualification

- Much is written
- Other industries, different approaches
- Exercise care: Define the situation first
- Goal: *Not* primarily to save money!
- Goal: To know and evaluate any associated risks, so as to allocate resources wisely



RM Qualification

Why Do It?

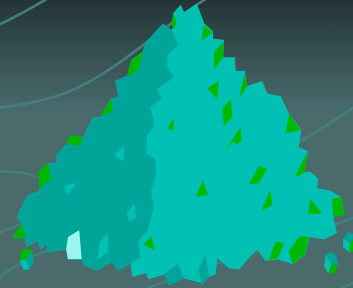
Develop a history of materials

- Lot consistency
- Resolve lot discrepancies (failures)
- Recall notifications

Confirm supplier's testing is accurate

Benefits:

- Quality/Regulatory security
- Supply chain, cycle times, efficiency



Risk Management: Supplier

Business issues: Capacity, lead time, back order, financial solvency and stability; mergers and acquisitions, long term reliability

Compliance issues: Adequacy of quality systems, change notification, compliance with appropriate standards, suitability for use; safety to end user



Triage Approach

- New/Unknown
- Qualified
- Highly qualified or certified
- Disqualified
- On HOLD for cause

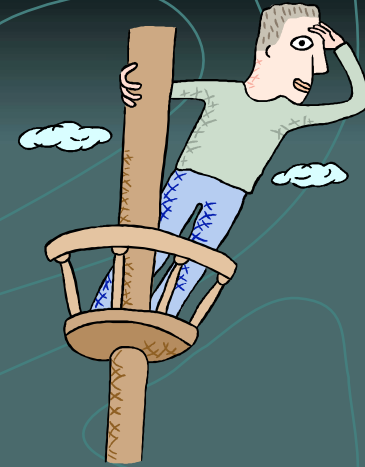


Allocate your resources based on risk

Supplier Qualification

● Strategies

- Intense Supplier Qualification
- Contracts and agreements
- Intense Product or Material Testing
- Hybrid approaches



Supplier Qualification Status

- A flow chart in the SOP and a document trail are most helpful with this type of system
 - Maintain a list of supplier-RM combinations and status information

New

Provisional

Approved

Blocked

Qualified/Certified



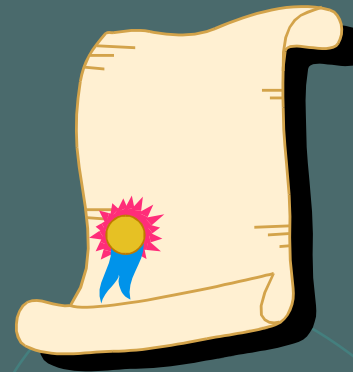
Reasons to Block a Supplier



- Lack of traceability of animal-derived RMs
- Under severe regulatory action
- Serious and repeated compliance concerns
- Data showing RM is not suitable for use
- Others...

Reasons to Upgrade Supplier Status

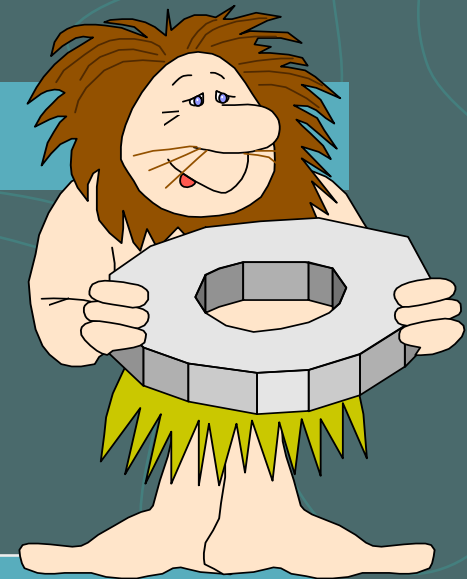
- Track record over time:
 - Audits, use of RMs, confirmatory tests
 - Purchasing contracts



Risk Management: Raw Material

● Issues:

- Suitability for use
- Process performance
 - Purity, grade, stability, residues
- Traceability, documentation
- Safety to end user
- Availability
 - Capacity, lead time, reject rate...



Categories of RMs

- Product constituents: Media, Buffers, Excipients
- Manufacturing Aids with Product Contact: Filters, gaskets, tubing
- *Manufacturing Aids without Product Contact: Sample tubes, pH buffers, gloves
- Packaging components
 - Product Contact: Vials, Bulk Container, Caps, Stoppers
 - Other: Crimp Caps, cartons, boxes, **Labels***

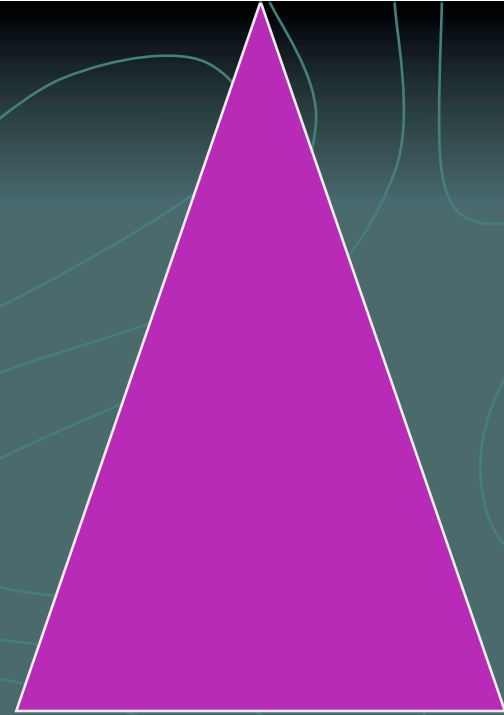
Raw Material Triage

● Critical (You define this)

- Excipients
- Active starting materials
- Material near edge of failure, your process
- Other criteria (cost, capacity, safety)

● Non-critical

- Well defined chemically; compendial;
- In-process use



Criticality and Testing:

Apply ANSI Z1.4

START
Non-critical RM

2 of 5 consecutive
lots rejected

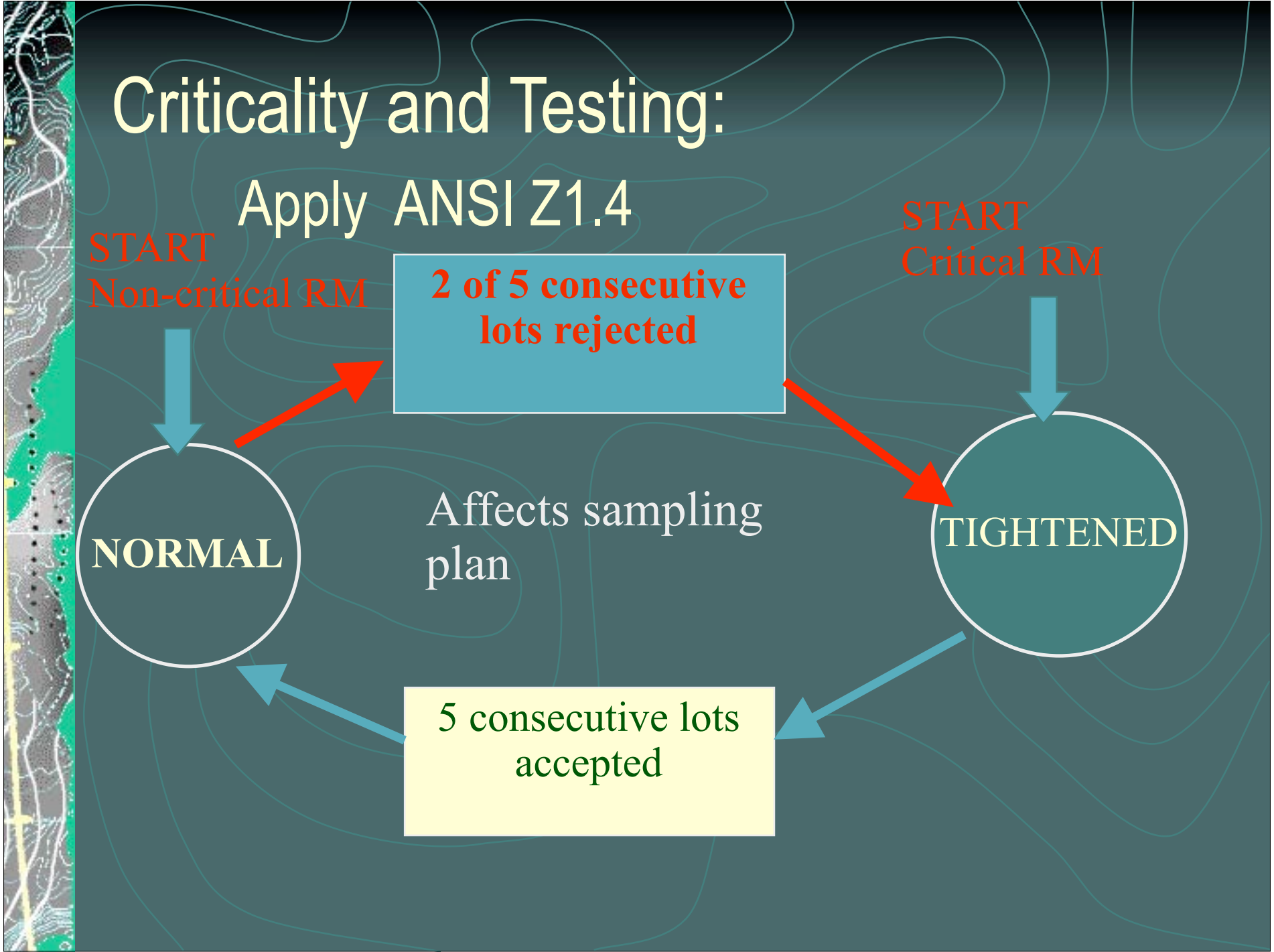
START
Critical RM

NORMAL

Affects sampling
plan

TIGHTENED

5 consecutive lots
accepted

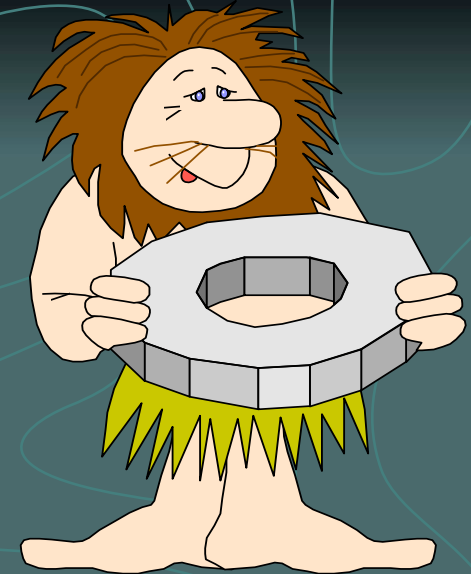
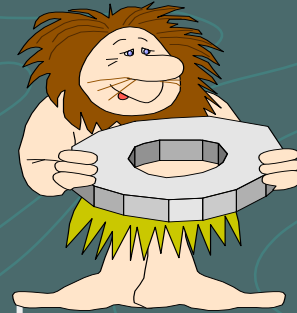


Raw Materials Qualification

- Define “Skip Lots” for abbreviated testing
 - Identification test(s) only
 - ID, Assay, and water/moisture
- What happens in case of a failure?
 - Build in a consequence (corrective action)
 - Revert to “full test” only
 - Revert to “unapproved” status

Raw Material and Supplier Qualification

- Are linked
- Are usually done in tandem
- Does qualifying one RM also qualify other RMs from the same supplier?
- Are RM qualification data portable to another supplier?



Build Flexibility Into Your Program

Respond to negative events with automatic changes in testing

Increased
Testing/audits

Normal
testing/audit

Reduced
Testing/audit

Respond to positive events with automatic changes in testing and in audit frequency and depth

Switching Rules: ANSI Z1.4

START

Last 10 Lots Accepted:

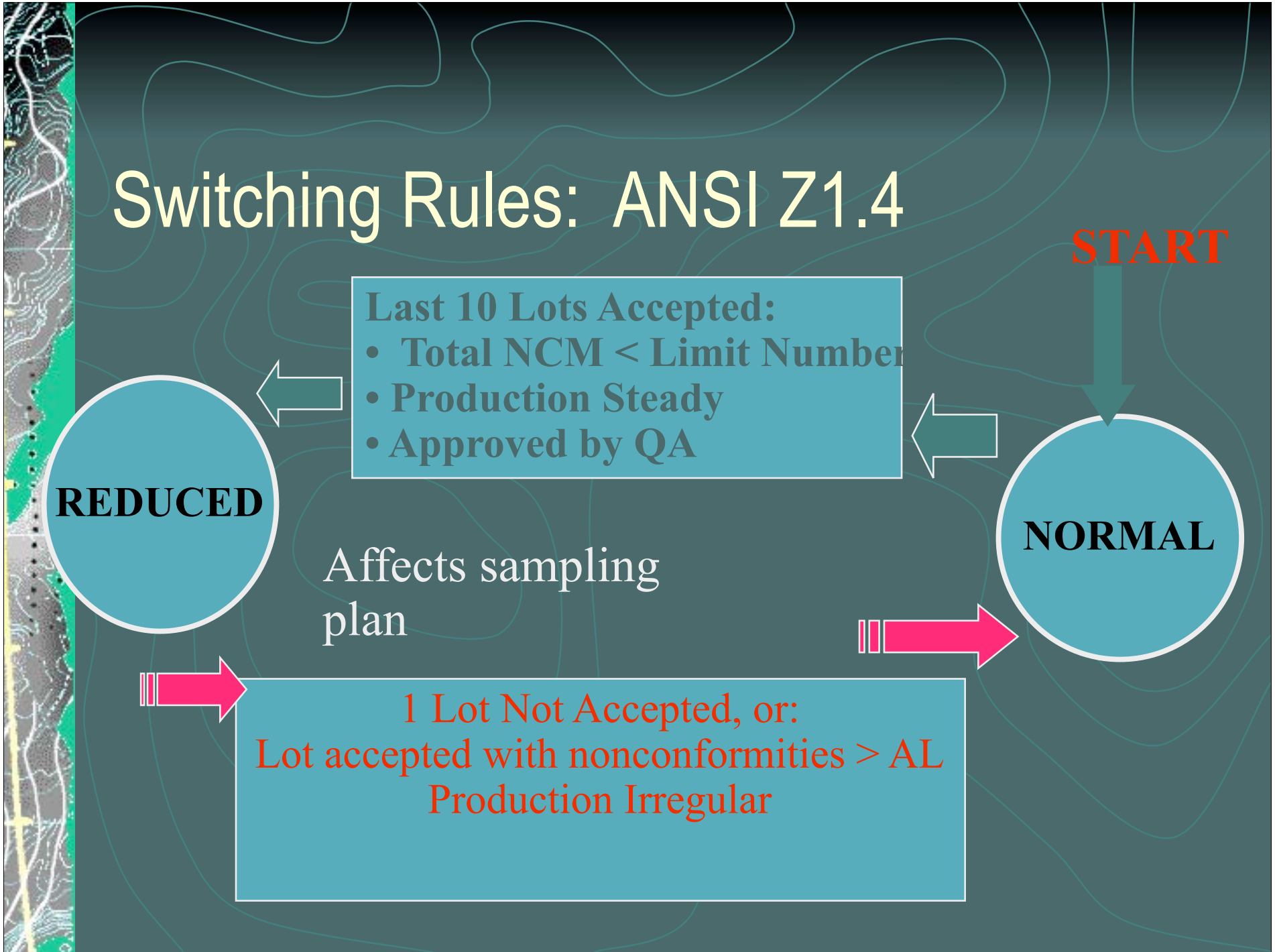
- Total NCM < Limit Number
- Production Steady
- Approved by QA

REDUCED

Affects sampling
plan

NORMAL

**1 Lot Not Accepted, or:
Lot accepted with nonconformities > AL
Production Irregular**



Switching Rules: ANSI Z1.4

Last 10 Lots Accepted:

- Total NCM < Limit Number
- Production Steady
- Approved by QA

REDUCED

NORMAL

1 Lot Not Accepted, or:
Lot accepted with nonconformities > AL
Production Irregular

START



Applying Z1.4 Concepts to Supplier Qualification

Certified: 10 lots full, audit score NLT 90%

Qualified: 10 lots full test and 90% score (no
audit), OR

3 lots full test, audit favorable, and 90%

Approved: 3 lots pass full testing

(1 lot only if vendor already approved)

Provisional: 1 lot full testing and MRB approval

Restricted: No procurement permitted

Example

Example

New RM from: NEW SUPPLIER

To use first lot:	Full testing and questionnaire
To qualify RM:	3 lots full testing, evaluation
To reduce testing:	3 lots full testing and evaluation

New critical RM NEW Supplier

To use first lot:	Full testing and audit
To qualify RM:	3 lots full testing and audit
To reduce testing:	10 lots full testing, audit; or never?

Putting it all together

RM testing data

Supplier audits, evaluations

RM Specification

Qualifying supplier's laboratory

QC Test qualification

Successful process use of RM/supplier

Contracts
Agreements

State of
Control
And
Predict-
ability

Control Systems: warehouse, Purchasing, Receiving

Discussion



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