SSD Quality Assurance and Quality Control

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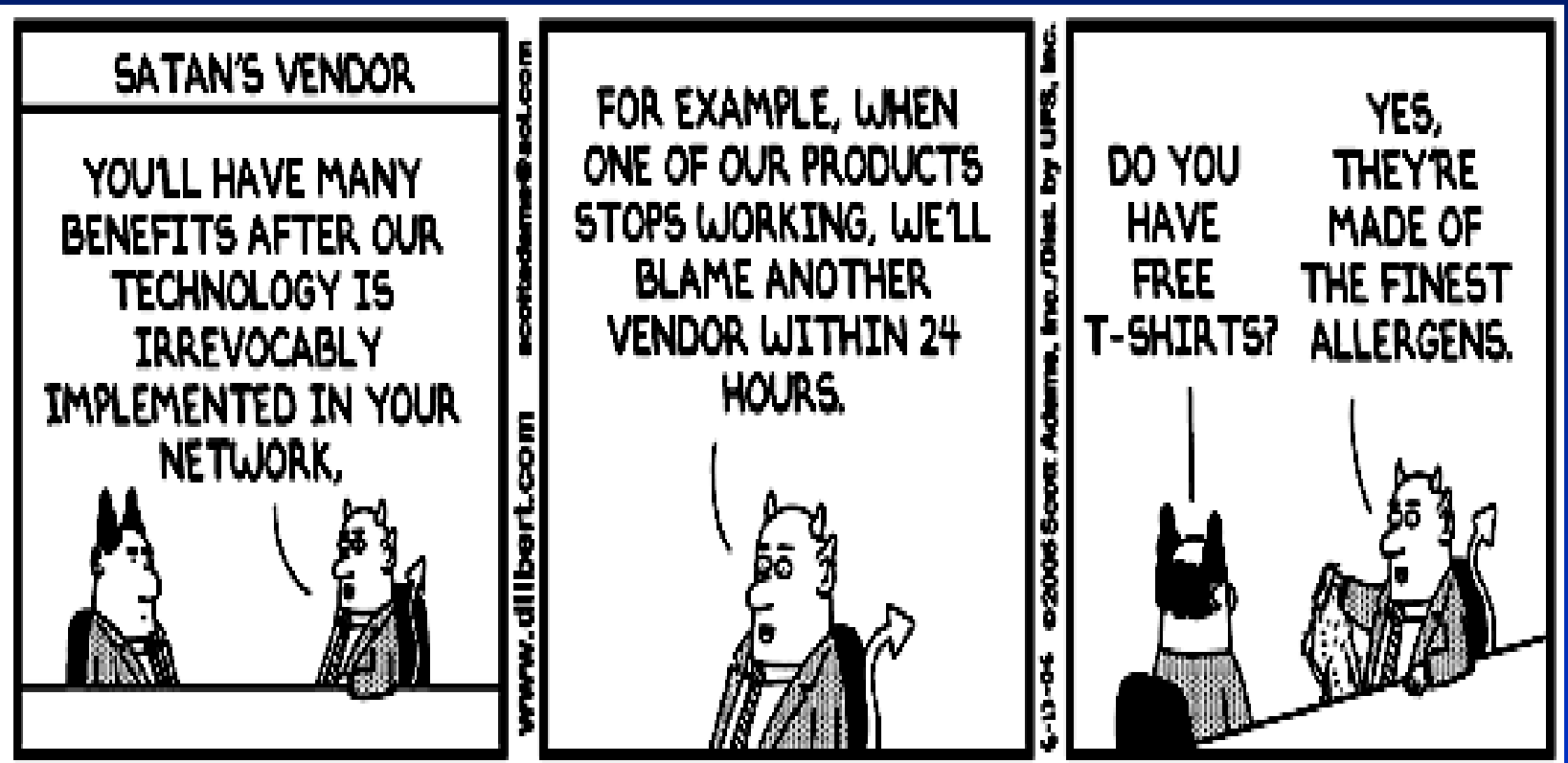
SATAN'S VENDOR
YOU'LL HAVE MANY BENEFITS AFTER OUR TECHNOLOGY IS IRREVOCABLY IMPLEMENTED IN YOUR NETWORK.
www.dilbert.com scottadams@aol.com
FOR EXAMPLE, WHEN ONE OF OUR PRODUCTS STOPS WORKING, WE'LL BLAME ANOTHER VENDOR WITHIN 24 HOURS.
DO YOU HAVE FREE T-SHIRTS?
YES, THEY'RE MADE OF THE FINEST ALLERGENS.
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- Mr. Jones related an incident from "some time back" when IBM Canada Ltd. of Markham, Ont., ordered some parts from a new supplier in Japan. The company noted in its order that acceptable quality **allowed for 1.5 per cent defects (a fairly high standard in North America at the time).**
- The Japanese sent the order, with a few parts packaged separately in plastic. The accompanying letter said: **"We don't know why you want 1.5 per cent defective parts, but for your convenience, we've packed them separately."**

Airline Service Log

Here are some actual logged pilot complaints and responses
> P = the problem logged by the pilot,
> S = the solution and action taken by engineers.

This airline, by the way, is the only major airline that has never had an accident.

- > P: Left inside main tire almost needs replacement.
- > S: Almost replaced left inside main tire.

- > P: Dead bugs on windshield.
- > S: Live bugs on back order.

- > P: Autopilot in altitude hold mode produces a 200 feet per
- minute descent.
- > S: Cannot reproduce problem on ground.

- > P: Evidence of leak on right main landing gear.
- > S: Evidence removed.

- > P: Something loose in cockpit.
- > S: Something tightened in cockpit.

- > P: DME volume unbelievably loud.
- > S: DME volume set to more believable level.

- > P: Friction locks cause throttle levers to stick.
- > S: That's what they're there for.

- > P: IFF inoperative.
- > S: IFF always inoperative in OFF mode.

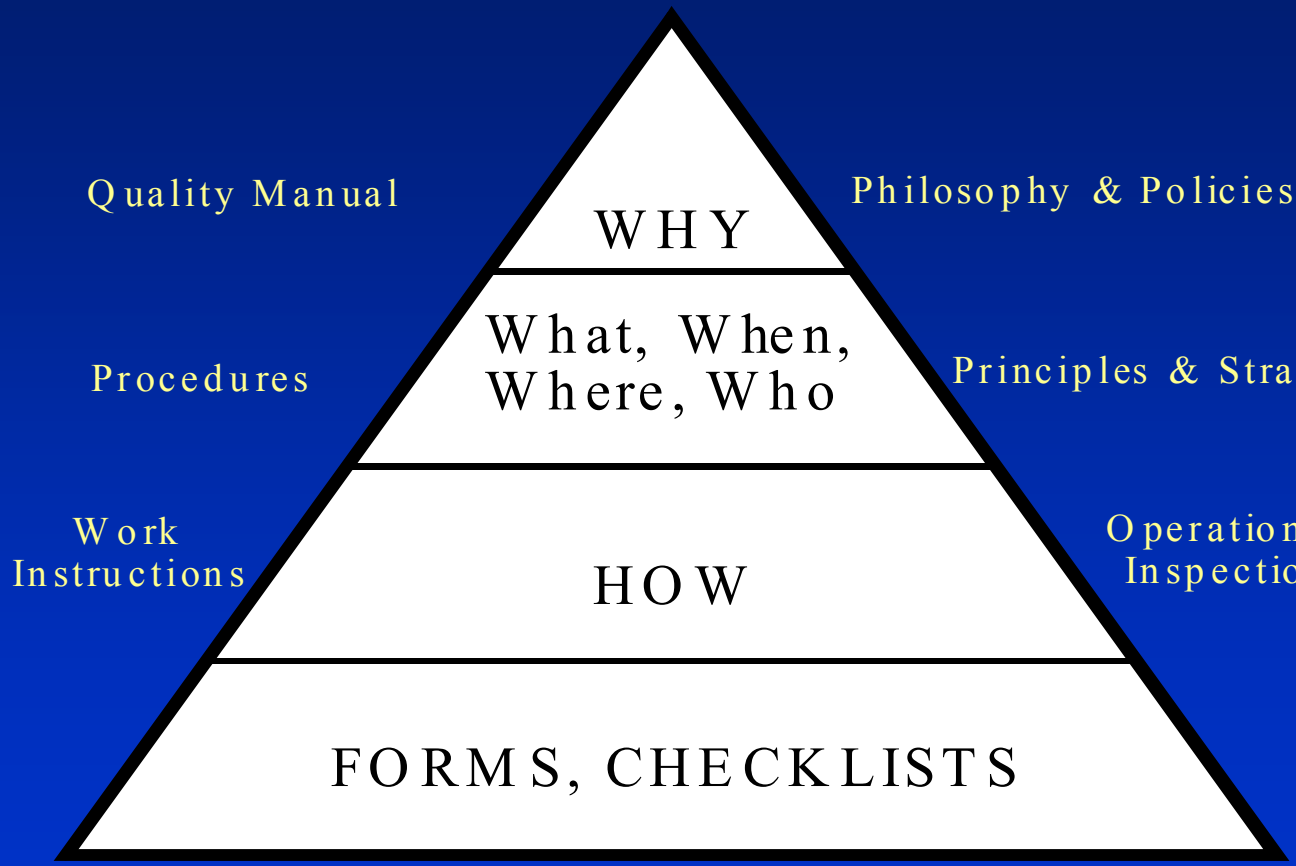
- > P: Suspected crack in windshield.
- > S: Suspect you're right.

- > P: Test flight OK, except auto-land very rough.
- > S: Auto-land not installed on this aircraft.

SSD Quality Assurance (QA)

- The planned and systematic actions necessary to provide confidence that a firm or product will perform satisfactorily and dependably.
- Usually in the form of a manual. Many vendors had control program items within the QA Manual.
- Defines the theory or philosophy of the program

Quality Document Pyramid



Quality Control (QC)

- The means to control and measure characteristics of an item, process or facility to the established requirements.
- Usually in the form of detailed procedures. Not necessarily in one manual. Sometimes listed on drawings.
- An element in implementing the QA program.

Goals of SSD QA/QC review

Must ensure that prior to distribution:

- leak test performed, no removable contamination
- radiation profile does not exceed specified limits
- on/off mechanism works properly
- all safety features work properly and are reproducible/dependable.
- unit meets specifications in the application (e.g. materials, dimensions, assembly, labels).

Goals of SSD QA/QC review (cont.)

Measures must be in place for traceability and accountability:

- training records
- records of fabrication
- design changes are documented and reported
- records of test results, acceptance inspection
- records of audits

Implementation of QA/QC

QA/QC philosophy must originate with ownership/ management.

QA/QC provides a system for

- consistent quality
- elimination of root cause for errors
- compliance with specifications

QC provides such measures, but

- final QC may require disassembly, or destructive testing
- in-process QC corrects errors, not cause

Examples of NRC QA Requirements

The Code is a set of requirements that is adopted by government bodies - local, state, or federal. A Code has the force of law.

- 10 CFR 50, App. B - nuclear reactors
- 10 CFR 71, Subpart H - transportation
- 10 CFR 72, Subpart G - spent fuel

QC for Sealed Sources and Devices

NRC requirements dispersed in the regulations

- Part 32.14(5) - applications
- Part 32.22(a)(2)(xv) - self-luminous products
- Part 32.26(b)(15) - gas and aerosol detectors
- Part 32.51(a)(2) - generally licensed items
- Part 32.53(b)(5) - luminous devices for aircraft
- Part 32.57(b)(5) - Am-241 calibration sources
- Part 32.61(b)(5) - Sr-90 ice detectors
- Part 32.74(a)(2)(v) - medical equipment
- Part 32.110 - sampling procedures
- Part 32.210(c) - QC in registration

QA/QC for Sealed Sources and Devices

- **"Quality Control and Quality Assurance," in Section 10.7 (and App. G.), "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and registration," NUREG-1556, Vol. 3, Rev. 1.**

- "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," NRC Regulatory Guide 6.9.

Standards - Examples

- ANSI/ISO/ASQC 9000/Q90-1994, “Quality Management and Quality Standards - Guidelines for Selection and Use.”
- **ANSI/ISO/ASQC Q9001 - 2008, “Quality Management Systems - Requirements” (see NRC position in SECY-03-0117, dated July 9, 2003 or in NUREG-1556, Vol. 3, Rev. 1.**
- NQA1 - “Quality Assurance Program Requirements for Nuclear Facilities”
- ANSI/ASQC Q1-1986, “Generic Guidelines for Auditing of Quality Systems.”

NRC Position on ANSI/ISO/ASQC Q9001

- See (1) SECY-03-0117, dated July 9, 2003 or (2) NUREG-1556, Vol. 3, Rev 1.

- QA/QC program should include additional provisions which addresses the specific issues involved in the fabrication of sealed sources and devices such as:

  - QA/QC program must stress safety;
  - management is responsible for product not vendors/suppliers;
  - specify who approves documents/changes;
  - full design conformity in accordance with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling), using sampling methods that meet the provisions of 10 CFR 32.110 or equivalent;

NRC Position on ANSI/ISO/ASQC Q9001 (cont.)

- acceptance testing specified;
- all units are leak tested to 0.005 microcurie (185 Bq);
- all units are tested for proper operation of all safety features;
- all units are verified that the radiation levels do not exceed the maximum values stated in the application;
- QA/QC of installation operations;
- software controls, including software development, verification and validation;
- product traceability and disposition of nonconforming items;
- Inspection hold points must be clearly defined;
- independent internal and external audits;
- notification of customers about defects; and,
- indoctrination, training, qualification and evaluation of personnel specified.

Elements of QA

- Organization
- QA Program with signatories
- Design Control
- Personnel Training
- Document Control
- Procurement Control of Purchased Material, Equipment and Services
- Inventory Control of Materials, Parts and Components
- Control of Production/Special Processes

Elements of QA (cont.)

- Internal Inspection/Testing
- Control of Measuring and Test Equipment
- Handling, Storage, Shipping
- Nonconforming Materials, Parts, and Components
- Customer Complaints
- QA Records
- Audits

Organization

- Vendor's organization should be explained (e.g. listing of the chain of authority, flowchart, etc.).
- Each person's responsibilities should be listed (usually in their job description).
- The QA/QC Manager should report directly to someone in upper management. Manager must be free from cost and schedule constraints. Manager usually has QA/QC as small part of duties.
- The upper management should have continued involvement in the QA/QC Program. *Weakness*

Design Control

- There should be procedures for processing all activities associated with design. The procedures should ensure the correct revision of drawings, procedures and documentation are available to each department involved. *Weakness - old revisions not always retrieved.*

- Procedures should ensure that all documentation is complete and will ensure the product is manufactured according to specifications. Notification of regulatory agencies of changes must be included.

Material and Service Procurement

- Materials and Services include: calibration, welding, inspecting, raw materials, sub-assemblies, etc.
- All services or materials received should ensure the final product meets specifications.
- The company should have a list of approved suppliers for each item they order.
- Orders should include all necessary information or reference prior orders or a contract.

Material and Service Procurement (cont.)

- Two methods to ensure compliance with the specifications are:
  - Inspection of the suppliers' QA/QC programs. *Weakness - usually inadequately performed.*
  - Inspection of sample lots received from each supplier.
- If the suppliers' QA/QC programs are inspected, periodic inspection of sample lots should be performed in addition to visual inspection of orders.

Inventory

- Includes inventory of raw materials, sub-assemblies and finished products
- Inventory procedures should include:

  Special handling, marking, tagging, labeling, segregating, paperwork controls, handling of non-conforming materials, accountability of material that has a shelf-life, and ensure that the proper material and sub-assemblies are used in the assembly process.
- Physical inventories should be performed periodically

Production and Assembly

- Assembly procedures should include step by step instructions including the equipment and qualifications of the worker needed to perform the task. *Weakness - usually left to worker.*

- Should also include at what points in the process to perform inspection and testing, i.e. hold points and witness points.

Inspection and Testing

- Procedures should exist for receipt, in-process and final inspection and testing.
- All procedures should include acceptance criteria, points for in-process inspection and testing, provisions for by-passing inspection, and provisions for non-conforming materials.
- Sample sizes selected during inspection should provide proof of quality; e.g., conform to Part 32.110 or equivalent.
- All inspections should be documented including results, date of inspection and person performing the inspection.

Inspection and Testing (cont.)

- Procedures should include segregation of items which have not been inspected or have failed inspection. *Weakness*.
- NRC practice calls for 100% operational check and 100% removable contamination testing prior to shipment.

Equipment

- A historical equipment log should be kept on each piece of equipment used to manufacture the product or used to ensure the product is manufactured to the correct specifications.
- Calibrations should be traceable to NIST and frequency should be dependent on the stability of the equipment.
- All equipment should be marked with its calibration date, date due calibration and the person or firm which performed the calibration.
- Equipment which requires special handling or storage or has special procedures for use should be marked accordingly and the procedures must be kept on file.

Personnel

- Each workers qualifications should be on file.
- If training was performed in-house, the training procedures should be documented. *Weakness*.
- If training is performed outside the organization, a certificate of course completion should be on file.
- Supervisors should have access to the employees qualification records. *They usually do but don't bother to check.*

Non-conforming Materials

- Procedures should include non-conforming materials found through receipt, in-process and final inspections and testing.
- Procedures should include segregation of non-conforming materials.
- There should be procedures for re-work and re-inspection. *Weakness - usually left to worker.*

Packaging and Transportation

- Procedures should apply to sub-assemblies (e.g. to subcontractors) and final products (e.g. to distributors or customers).

- Procedures should include:

  Packaging of the product, form of shipping, bracing needed during shipping, labeling of the package, and documentation which must accompany the shipment.

Defects and Customer Complaints

- Applies to defects found during production and those reported by customers.
- Must have procedures to inform employees how and when to file 10 CFR Part 21 reports.
- Procedures for receiving reports of defects from customers should include:

  Device type, model number, serial number, name of complainant, nature of complaint, reply to complainant, corrective action taken, analysis of the failure and cause of the failure.

Defects and Customer Complaints (cont.)

- Procedures should include:
  - Analysis of the failure, corrective action taken.
  - Notification of all effected customers (e.g. if a generic problem).
  - Notification of regulatory agencies.
  - Notification of QA/QC department and department responsible for the defect and trend analysis (at least performed yearly).

Weakness - usually done on a case by case basis, should include trending.

Records and Documentation

- For each component of the program the QA/QC department should have on file written, up-to-date procedures and records indicating that each component of the program is being implemented properly.
- All records should be kept for three years or life of the product.

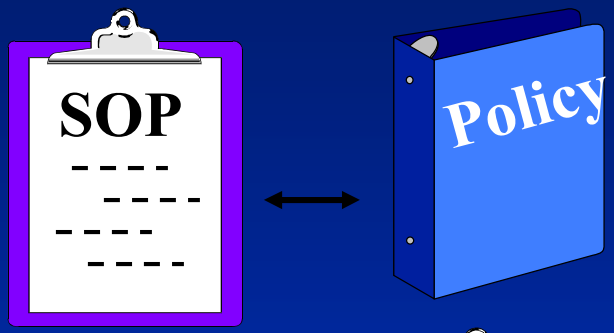
Quality System Audit

- Compares '*what is'* to '*what is supposed to be*.'
- Program components must be properly documented. It is impossible to determine the degree of compliance with an undefined state.
- For a quality system audit, the quality manual is the definition of what is supposed to be.

Audit Types

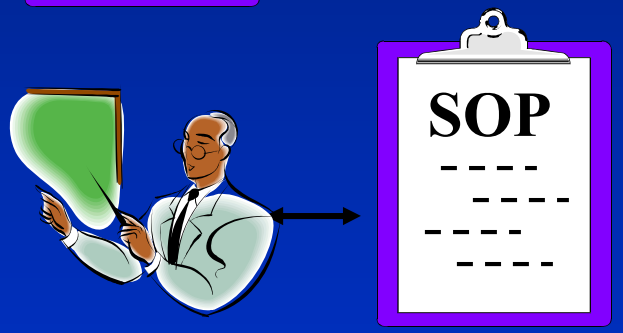
Policy Audit

compares written policies and procedures with standards and specifications



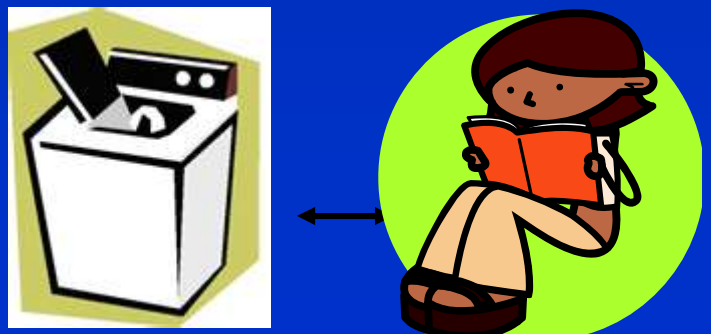
Practice Audit

compares actual practices with established procedures.



Product Audit

compares performance of a product or service with its specifications.



Audit Types – cont'd

First-Party Audit → **Quality auditor in *your* organization audits *your* quality system.**

Second-Party Audit → **Quality auditor from your source of funds audits *your* quality system.**

Third-Party Audit → **Lloyds QA audit team audits *your organization's* quality system.**

Quality System Audit (cont.)

- Includes both audits of vendor's program and suppliers' programs.
- Vendor's program audits should be performed periodically.
- Vendor program audits should be performed by someone outside the QA/QC program or by an outside firm.
- Procedures should include re-auditing deficient areas*

**Common weakness in new QA programs.*

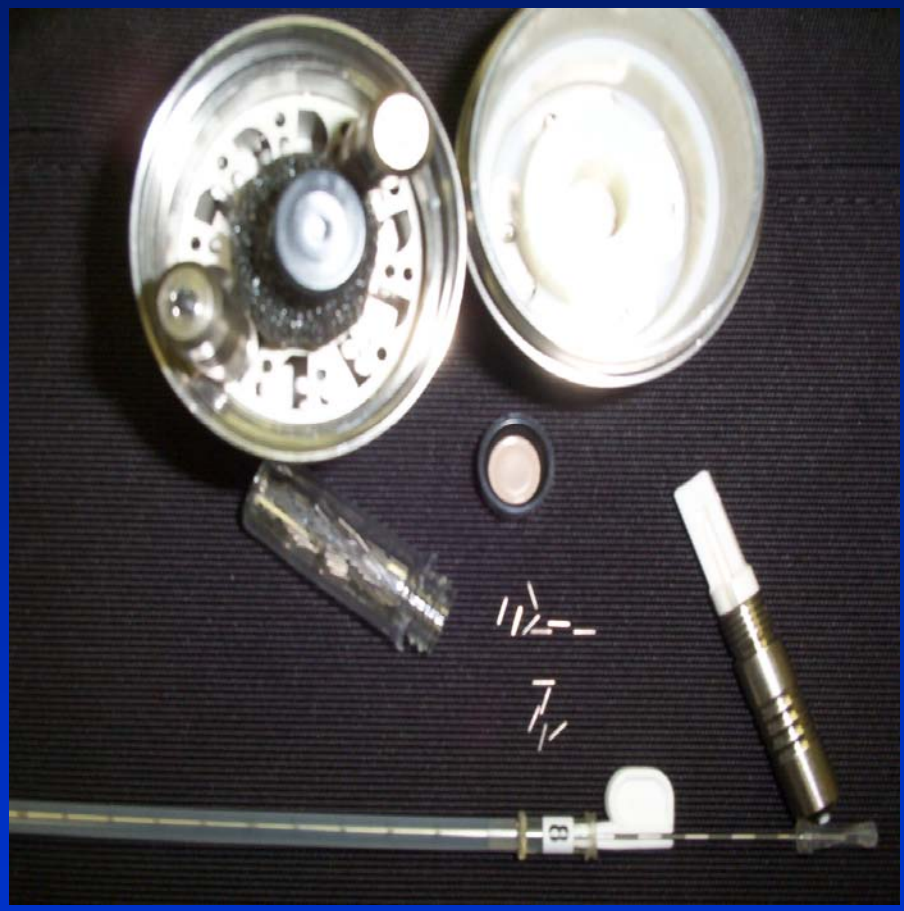
Steps in Performing a Quality Audit

- Initiation - routine, customer complaint, defect.
- Planning - review causes, establish trends, choose standards, prepare checklists.
- Implementation - interview staff, test product, check records, detailed notes.
- Reporting – review findings, make corrective recommendations, draft/present report, set deadline for corrections.

QA Inspection Results

- Management QA Review meeting minutes not maintained.
- Internal System Audits results not maintained for numerous manufacturing processes.
- Design and Document Control records not maintained for new designs or submitted to Agency for review.
- Customer Complaints/Defects not investigated or resolved:
  - 8 cases of shutter damage from vibration.
  - Surface effects on sealed sources.
  - Report of irregular dimensions.
  - Leaking source after service by 3rd party.
- ISO audit findings not corrected in over 3 years.

QA/QC Facilities and Equipment

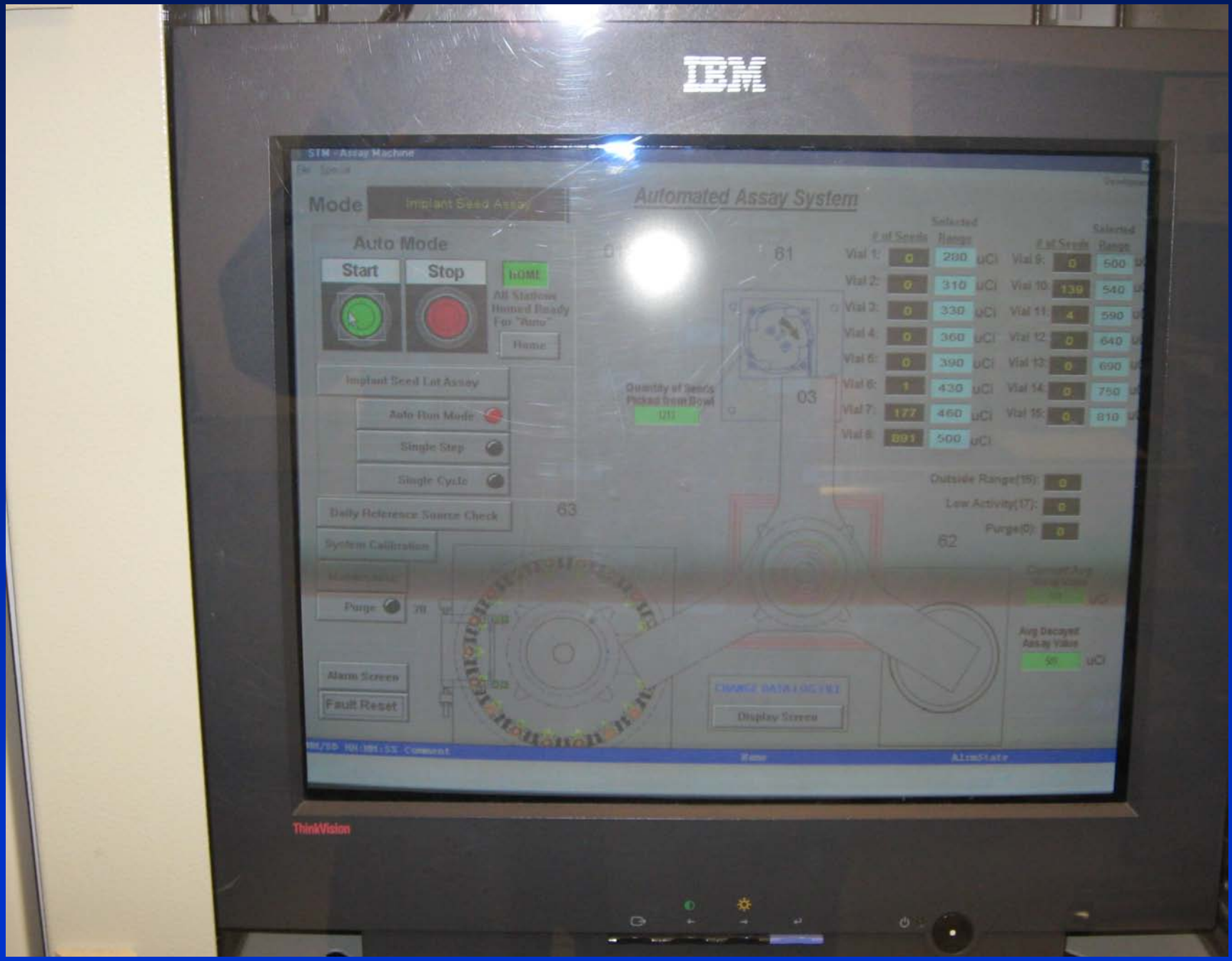



BOX 6
CHECK ONE
GemOro
GemOro


Box 6


VWR


IBM


IBM
STM - Assay Machine
Mode
Implant Seed Assay
Automated Assay System
Auto Mode
Start
Stop
HOME
All Stations Homed Ready For "Auto"
Home
Implant Seed Lot Assay
Auto Run Mode
Single Step
Single Cycle
Daily Reference Source Check
System Calibration
Purge
Alarm Screen
Fault Reset
Display Screen
Quantity of Seeds Picked from Bowl
# of Seeds
Selected Range
Vial 1: 0 280 uCi
Vial 2: 0 310 uCi
Vial 3: 0 330 uCi
Vial 4: 0 360 uCi
Vial 5: 0 390 uCi
Vial 6: 1 430 uCi
Vial 7: 177 460 uCi
Vial 8: 691 500 uCi
Vial 9: 0 500
Vial 10: 139 540
Vial 11: 4 590
Vial 12: 0 640
Vial 13: 0 690
Vial 14: 0 750
Vial 15: 0 810
Outside Range(15): 0
Low Activity(17): 0
Purge(0): 0
Avg Decayed Assay Value
61
62
63
03
ThinkVision


ASC001
ALARMS
MAIN
OPERATOR SCREEN
999
85
85
START
999
85
FAULT
STOP
0
0
0
RESET
PRINT


PLANAR
5


DELL
READYLINK IMAGING
ISOSLEEVE IMAGING SYSTEM


DELL
AUTORADIOGRAPH IMAGING SYSTEM

Thank You!

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