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AQS 115 – EXAM #3
(48 pts)

1. The primary purpose of conducting internal audits is to
 - a. Find problems
 - b. Interview staff
 - c. Review the effectiveness of the QMS
 - d. Identify issues with procedures
2. A conflict of interest threatens which of the following audit attributes?
 - a. Objectivity
 - b. Performance
 - c. Completion
 - d. Clarity
3. Which audit listed below would typically require more time to prepare?
 - a. Process
 - b. Procedure
 - c. Product
 - d. Quality System
4. An auditor's responsibilities include
 - a. Taking action on important audit findings
 - b. Complying with audit standards and procedures
 - c. Providing resources needed by the audit team
 - d. Determining the audit need scope and purpose.
5. Audit team members are responsible for
 - a. Recommending specific corrective actions
 - b. Initiating most second party audits
 - c. Collecting audit evidence
 - d. Defining the scope and purpose of the audit.
6. During audit preparation, an audit team would
 - a. Prepare an exit meeting summary
 - b. Review available and appropriate documentation
 - c. Conduct interviews
 - d. Schedule any anticipate follow-up audits
7. The audit agenda is typically prepared
 - a. In the opening meeting with the auditee
 - b. At the same time as the annual audit schedule
 - c. By the audit team
 - d. By the audit team leader
8. The forward-tracing technique has which of the following advantages
 - a. Allows for auditee personnel to be juggled
 - b. Assists the auditor to understand process flow
 - c. Is practical for follow-up audits
 - d. Permits maximum audit flexibility
9. Which of the following would be considered objective evidence?
 - a. Non-electronic control of documents
 - b. Key operator comments about specification violations
 - c. Auditor observation of revision controlled blueprints being used
 - d. No operating training recorded in last six months

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10. The most widely used technique for distinguishing between chronic and insignificant problems is:
 - a. Pareto diagram
 - b. Control chart
 - c. Cause and effect diagram
 - d. Scatter diagram
11. Checklists are useful during audits because
 - a. They promote an economical use of time
 - b. They promote flexibility
 - c. They permit randomness in audit coverage
 - d. They can be substituted for an audit report
12. During an audit, an auditor discovers a set of unapproved, handwritten work instructions. As a result of this observation, he auditor should
 - a. Add more questions to the checklist
 - b. Determine if this is an isolated incident or chronic deficiency
 - c. Ask that the work instruction be reviewed and approved
 - d. Keep the document as evidence of the deficiency
13. Following an audit and report-out, checklists should be
 - a. Maintained a reference of the auditee's response and documentation
 - b. Discarded, as the audit report is the only required deliverable
 - c. Copied and sent to the auditee
 - d. Shredded to ensure that proprietary information remains intact
14. The audit report should include
 - a. Details of how the audit team was selected
 - b. Identification of person(s) who prepared the checklists
 - c. A summary of audit results and findings
 - d. Qualifications of personnel who performed the audit
15. An audit is an organized method of
 - a. Pinpointing responsibility for error
 - b. Writing checklists
 - c. Assuring that personnel are adequately trained
 - d. Finding out how business is actually being conducted
16. Audit schedules should be
 - a. Periodically reviewed and modified
 - b. Established annually and rarely modified
 - c. Approved by all subcontractors
 - d. Established by top management
17. When observing recorded data from various sources and formats, outliers are noted to be:
 - a. Below the lower control limit in a control chart
 - b. Unusual observations in any data arrangement
 - c. Higher than the average value on a data sheet
 - d. Data not fitting into a bell shaped curve
18. The best description of sampling used when auditing is
 - a. Contained in ANSI/ASQ Z1.4
 - b. Taking a few representative pieces off the top
 - c. The selection of random items

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- d. A sequential selection process

Review each of the following scenarios and answer the questions that follow. (5 pts each)

Incident #1:

The Quality Manager at Widget, Inc. noticed an increased number of defective widget component parts being supplied by the Ready Company. The corrective action reports as received from both the Ready Company and feedback from Andy (the resident inspector) didn't seem to affect the increase in rejections. .

The Quality Manager selected Andy to conduct an audit of Ready's quality system. Andy who had been assigned to the Ready location for two years, developed a checklist based on a Pareto analysis of complaint items and began the special audit the next day, principally because he did not want to alert Ready to take any "special precautions".

(Note- Andy is employed by Widget, Inc. but works on-site at Ready Company)

19. Is Andy an acceptable choice for Auditor? Why or why not?

Andy is NOT an acceptable choice as an auditor. Because he is the on-site inspector and has been there for 2-years he would not be considered independent or objective. His bias is hinted at regarding the corrective action reports and lack of effectiveness regarding rejection reduction.

20. In preparing for the audit, Andy was

- a. Too narrow in his approach
- b. Thorough in his preparation
- c. Correct, but he overlooked the products that were performing well
- d. Correct, but he should have considered sales volume?

His approach is narrow in that he looked only at complaints which may or may not be related to increase in rejections. There was no indication of conducting an investigation to understand why rejections have been increasing.

Incident # 2:

In the shipping area, the auditor stops to look at six finished valves, serial numbers A345 to A350, in individual cartons. The auditor asks the shipper why the items are packed in corrugated cardboard instead of plastic containers as required by the packaging work instruction PW18, revision 2. The shipper replied that the shipping supervisor had instructed them to use corrugated cardboard when they ran out of plastic containers two weeks ago.

Area under Review: Shipping / Packaging
ISO 9001:2015 reference: 8.5.4

Is this a nonconformance? Y or N

If yes, what is the requirement and what is the finding?	If No, why is this considered conforming?
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<p>Requirement:</p> <ul style="list-style-type: none">• Per 8.5.4; "The organization shall preserve the outputs ... to the extent necessary to ensure conformity to requirements. Note: Preservation can include...packaging...."• SOP PW18 (Rev 2) requires plastic containers <p>Finding: Via observation and interview six finished products S/N A345 to A350 were packaged in corrugated cardboard rather than plastic.</p>	
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Incident #3:

While on the manufacturing process tour, the auditor recorded the following data related to four gages and requested the calibration records for review. The results of the review are summarized below.

- Polar 500 leak tester ID# 529 was calibrated on 30-Sep-2016. Techmaster calibration certificate #408 dated 03-Feb-2016 indicated next date should be 03-Aug-2016 based on six month cycle. Techmaster calibration certificate #3151 dated 30-Sep-2016 indicated equipment was found within calibration range, no adjustments were needed. A CAPA had been issued which indicated there was no risk to product as the tester was found to be within calibration range.
- Calipers ID# 2032 were calibrated on 04-Feb-2017 and the next calibration date is 04-May-2017. A review of the records found that the tool was calibrated every three months and was found to be within calibration range, no adjustments were needed.
- Scale ID# 40957 was calibrated on 13-Mar-2017 and the next calibration date is 13-Sep-2017. A review of the records found that the tool was calibrated every three months and was found to be within calibration range, no adjustments were needed.
- Optical Comparator ID#8930 was last calibrated on 15-May-2016. Photonics calibration certificate #215 dated 15-May-2015 indicated the next date should be 15-May-2016. Discussion with Calibration personnel revealed that Photonics is scheduled to come in next week (07-May-2016) to perform the calibration. This was confirmed via review of email correspondence.

Area under Review: Calibration

ISO 9001:2015 reference: 7.1.5.1, 7.1.5.2

Is this a nonconformance? Y or N

If yes, what is the requirement and what is the finding?	If No, why is this considered conforming?
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	<p><i>Requirement</i></p> <ul style="list-style-type: none">• <i>Per 7.1.5.2 When measurement traceability....measuring equipment shall be:</i> a) <i>Calibrated or verified at specified intervals....</i> <p><i>Rationale-</i> <i>Three of the four gages were calibrated within their specified range. A review of the individual tool records indicated overall consistency in meeting calibration schedules. The leak tester was calibrated late, but a CAPA had been issued that assessed risk.</i></p> <p><i>One observation does not indicate an out-of-control situation. Additional records could be reviewed if time permitted for further analysis.</i></p>
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Incident #4:

An internal auditor was interviewing the Purchasing Manager about supplier evaluations. The Manager stated that their criteria for selecting suppliers involves both getting samples of their supplier's product and completion of the SE-101 form regarding the evaluation. The Manager indicated that all of the suppliers listed on the Approved Supplier List has a SE-101 form on file. Browsing through multiple supplier files, Consultant's Inc., Outfitters LLC and Whack Corp. did not have an associated SE-101 form. When questioned on this, the Purchasing Manager stated that these suppliers were brought in on a recommendation from the Operations VP and that neither samples nor the SE-101 would be necessary.

Area under Review: Procurement

ISO 9001:2015 reference: 8.4.1

Is this a nonconformance? **Y** or N

If yes, what is the requirement and what is the finding?	If No, why is this considered conforming?
<p><i>Requirement:</i></p> <ul style="list-style-type: none">• <i>Per 8.4.1: Organization shall determine and apply criteria for evaluation, selection ...of external providers based on their ability... The organization shall retain documented information of these activities and any necessary actions...</i>• <i>Manager stated that form SE-101 was available for all suppliers.</i> <p><i>Finding:</i> <i>Neither samples nor the SE101 had been completed for three vendors (Consultants Inc., Outfitters, or Whack).</i></p>	

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Incident #5:

In the Engineering department, the auditor sees three products on a desk, serial numbers 222, 223 and 224. The Engineering Manager explains that these products came from Production because of difficulties identified during manufacture. The auditor asks what's wrong with them and if they're good or bad. The manager stated that he didn't know as the units had just come up early this morning from the midnight shift.

Area under Review: Identification and traceability

ISO 9001:2015 reference: 8.5.2

Is this a nonconformance? **Y** or N

If yes, what is the requirement and what is the finding?	If No, why is this considered conforming?
<p><i>Requirement:</i></p> <ul style="list-style-type: none"><i>Per 8.5.2: Organization shall identify the status of outputs with respect to monitoring/measurement requirements throughout production/service provision.</i> <p><i>Finding:</i> <i>Product serial numbers 222, 223, 224 found in the Design department did not have any identification of status</i></p>	

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Incident #6:

As an auditor for Healing Inc., you are touring Assemblers LLC facility. Per contract, the Healing Inc. catheters are manufactured at Assemblers LLC in a controlled environment. During the window tour it was observed that that 2 of the 10 employees had the fingertips of their gloves removed and had direct skin contact with the product. The vendor's SOP Doc #4.5 "Gowning Requirements" (Rev G) states that gloves are to be worn at all times in controlled environment areas. However, section 6.3.8 of the procedure also states that no gloves are to be worn where there is a safety concern for moving parts.

Area under Review: Environment for the operation of processes

ISO 9001:2015 reference: 7.1.4

Is this a nonconformance? Y or **N**

If yes, what is the requirement and what is the finding?	If No, why is this considered conforming?
	<p><i>Requirement</i></p> <ul style="list-style-type: none"><i>Per 7.1.4: Organization shall determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products/services.</i><i>SOP 4.5 Rev G states gloves must be worn in controlled environments, but then clarifies this requirement in Section 6.3.8 in the cases of safety concerns.</i> <p><i>Rationale –</i> <i>More information is needed such as what is the exact operation, is there safety concern? Is this a contamination risk – are there subsequent cleaning steps and/or sterilization processes</i></p>