

UT Southwestern
Medical Center

Biomedical Equipment Maintenance Audit

Internal Audit Report 22:09

March 1, 2022

Table of Contents

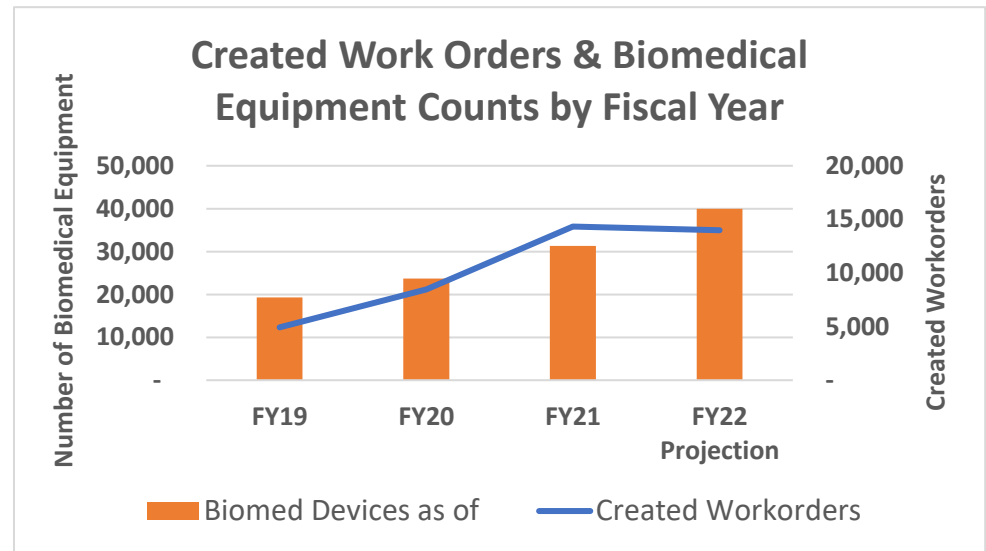
I. Executive Summary	3
• Background	
• Scope and Objectives	3
• Conclusion	4
II. Detailed Observation and Action Plans Matrix	7
III. Appendix	17
• Appendix A – Risk Classifications and Definitions	17

Executive Summary

Background

The Hospital Biomedical team (Biomed) reporting to the Director of Operational Logistics is responsible for the inspection, preventive and corrective maintenance of diagnostic and therapeutic biomedical equipment and medical devices deployed in hospitals, hospital-based clinics and ambulatory clinics. The responsibility of equipment maintenance pertains to the routine inspections and preventive maintenance of equipment as recommended by the original equipment manufacturers (OEM) and corrective repairs to restore equipment back to their optimal working condition. The Biomed team consists of one Manager, three Supervisors, and twenty-three service technicians. The Biomed team coordinates with Operational Logistics to account for deployed biomed equipment and perform periodic inventory. The Biomed team has support from the Hospital Logistics team performing equipment database analytics. Additionally, the Hospital Support Services Administration team was most recently tasked with performing quality assurance reviews of equipment records.

Operational Logistics uses the ATTAINIA application to manage biomedical equipment design, planning and acquisition. Individual biomedical asset records delivered and recorded in ATTAINIA are transmitted automatically to NUVOLO, the maintenance system used for entering service requests, generating equipment service work orders and generating service schedules. NUVOLO is built on the ServiceNow platform and contains over 35,000 capital and non-capital equipment records. There has been growth in the number of biomedical equipment and devices and the number of equipment maintenance work orders as depicted in the graph.



Scope and Objectives

The Office of Internal Audit Services has completed its Biomedical Equipment Maintenance audit. This was a risk-based audit and part of the fiscal year (FY) 2022 Audit Plan. The audit scope included maintenance activities for diagnostic and therapeutic biomedical equipment and medical devices deployed in hospitals, hospital-based clinics and ambulatory clinics for the period September 2020 through December 2021.

Executive Summary

The objectives of the audit were to assess the adequacy and effectiveness of controls in place to ensure:

- Timely and complete equipment maintenance and repairs
- Complete and effective monitoring
- Appropriate NUVOLO system access
- Compliance with policies, procedures and regulations

Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, substantive testing, and data analytics. We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

Conclusion

The biomedical equipment maintenance program is centralized with a system to support the equipment maintenance activities. However, there are opportunities to enhance the NOVOLO equipment maintenance system features including automating maintenance requests, performing proper data clean-up and implementing formal data management procedures. These enhancements would ensure better capture of critical information and tracking and reporting to better manage and monitor overall maintenance activities. A formal comprehensive documented equipment maintenance program is needed to ensure adequate and effective equipment maintenance and consistent practices throughout the equipment lifecycle across the health system. Biomed Department leadership is planning to automate the maintenance request process and implement a call center operation to provide improved quality customer service for equipment maintenance.

An assessment needs to be performed in coordination with Information Resources and Supply Chain Management to determine the most cost-effective way for the capture of vendor equipment manufacturer and third-party equipment warranty information. Currently, warranty information is not captured centrally in the NUVOLO system. There is not flagging in the purchasing or contracts systems to capture equipment with warranty or service agreements and there are no interfaces between these systems. This information is critical to reduce the risk of excess equipment maintenance costs for maintenance done internally and not through the contracted paid services and to prevent warranty voids or equipment maintenance issues due to non-compliance with warranty requirements.

Included in the table below is a summary of the observations along with the respective disposition of these observations within the UT Southwestern internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions.

Executive Summary

Priority (0)	High (0)	Medium (6)	Low (0)	Total (6)
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Key observations are listed below.

- **#1 Strengthen Oversight of Equipment Maintenance System Database Record Management** – Overall responsibility for managing biomedical equipment maintenance activities related data needs to be established to ensure the accuracy of information. The NUVOLO maintenance database contain incomplete outdated records and inaccurate or missing data values increasing the risk of the inability to locate equipment and untimely required maintenance.
- **#2 Improve Work Order Management and Establish Monitoring Procedures to Ensure Timely Completion of Equipment Maintenance** – New equipment inspection work orders (WOs) are not closed timely, are missing documentation of assignment, approval, equipment ID, or evidence of actual work performed making it difficult to validate whether new equipment inspections or maintenance had been performed.
- **#3 Enhance and Formalize Equipment Maintenance Service Request Processes and Monitoring Controls to Ensure Customer Satisfaction** – A formal standard process is not place for Hospital and Ambulatory departments to request corrective maintenance services with the Biomed team. Current requests are through phone calls or emails, increasing risk of not capturing all requests and inability to monitor and track maintenance requests.
- **#4 Capture Warranty and Equipment Maintenance Contracts Information in System to Ensure Compliance and Improve Equipment Maintenance Expense Management** – Equipment warranties or third party contracted services information is currently not captured in NUVOLO equipment records and not taken into consideration when creating work orders for equipment maintenance. This increases the risk of non-compliance with warranty requirements or excess maintenance cost for internal maintenance that could be done under contract.
- **#5 Formally Document the Biomedical Equipment Maintenance Program at the Health System Level** – A formally documented maintenance program at the health system level is not in place to ensure hospital and ambulatory operations are complying with the equipment maintenance program and effective equipment maintenance and decommissioning of equipment is properly tracked.
- **#6 Strengthen NUVOLO User Access Administration** – NUVOLO currently does not have a dedicated business owner for approving and updating user access, which increases the risk of inappropriate access going undetected.

Executive Summary

We would like to take the opportunity to thank the individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,

Valla F. Wilson, Vice President and Chief Audit Executive, Office of Internal Audit Services

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Executive Summary

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Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>1. Strengthen Oversight of Equipment Maintenance System Database Record Management</p> <p>Opportunities exist for improving overall biomedical equipment maintenance management. There is no overall accountability for ensuring equipment records are set up properly in the NUVOLO system and continual maintenance transactions are accurate and timely, to ensure proper biomedical equipment maintenance is performed. There were incomplete records with missing key input values such as individual risk scores, physical location, asset description, owning department, asset tag # and serial ID #, which increases risk of being unable to locate equipment for required maintenance in a timely manner, as well as risk of noncompliance with maintenance schedules. The following are examples of data deficiencies found in the NUVOLO database.</p> <ul style="list-style-type: none"> • Generic Asset ID # 1234 was used for 87 service requests and work orders (WOs) because the associated equipment records were missing a valid ID. The Biomed team closed individual WOs without identifying root causes. • An equipment record had 80 repeating preventive maintenance requests and WOs within the last year due to incorrect data entry of maintenance frequency in NUVOLO. 	<ol style="list-style-type: none"> 1. Develop a database cleanup and refreshing plan, allocate resources and set target date to identify records requiring updates for correction and resolution. 2. Reiterate responsibility and accountability of Biomed staff and management regarding data maintenance processes. Develop procedures on how to use the system. 3. Establish performance goals and expectations. Introduce dashboards and administer additional follow up training as needed. 4. Reemphasize monitoring and establish quality assurance activities. Introduce periodic tracking reports to highlight progress for repairs and records keeping. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The Biomed Department will conduct an annual data scrub of all medical devices listed in our CMMS (Clinical Maintenance Management System). This data scrub will involve running all of our 30,000+ medical devices and their associated records through an analytical software program that detects data discrepancies and marks them for correction. 2. We are creating new Biomed Supervisor positions. The newly created positions will be given monthly benchmarks that identify departmental goals and expectations for all maintenance processes that are completed. The results of these goals will be presented in the monthly Biomed Subcommittee for the monthly EOC committee. 3. The Department has established monthly, quarterly and annual dashboards that will display the performance of the Biomed department that can be shared and discussed with UH leadership. 4. The Biomed Department will implement a Quality Assurance team to monitor the quality of activities within the Department for repairs and record keeping. <p><u>Action Plan Owner:</u> Director, Operational Logistics</p>

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<ul style="list-style-type: none"> Equipment records reflecting installed status which were confirmed to be retired and no longer in service. <p>Migration of incomplete records from the prior system conversion in 2019 contributed to inaccurate records in the current system.</p>		<p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. Completed 01/31/2022 and to be repeated annually 2. 06/30/2022 3. 08/31/2022 4. 09/30/2022

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>2. Improve Work Order Management and Establish Monitoring Procedures to Ensure Timely Completion of Equipment Maintenance.</p> <p>New equipment inspection work orders (WOs) are not closed timely in NUVOLO with 58% of WO's being greater than 90 days.</p> <p>Additionally, WO's were missing documentation of assignment, approval, equipment ID, or evidence of actual work performed making it difficult to validate whether new equipment inspections or maintenance had been performed. Examples are below:</p> <ul style="list-style-type: none"> • Dated equipment records received in NUVOLO were not released into operation pending actual setup and installation. There were WO's over 180 days old with the oldest exceeding 34 months old from receipt date, which increases the risk of loss or missed scheduled maintenance. • WO's were closed out in NUVOLO without being assigned to staff and/or management approval documentation, which is a risk that the equipment maintenance was not performed. • Open and closed WO's did not reference an equipment ID # because equipment setup was incomplete as a result of the data field not being a required input value. 	<ol style="list-style-type: none"> 1. Conduct an assessment and work with the software vendor to require input values and management approval for specific data fields related to the WO setup and closeout processes. 2. Establish monitoring procedures to ensure WO's are properly addressed, information is properly documented and WO's are properly closed out. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The Biomed Department will work with NUVOLO to develop an installment to the current CMMS software (NUVOLO) that requires certain data fields to be completed before a technician can close out a work order. This workflow would also require Biomed Supervisor verification and would be audited monthly by our Quality Assurance team and the newly created Director of Clinical Engineering position. <p>If this workflow cannot be implemented within our current CMMS software, a new RFP will be issued to see what other CMMS programs are available that contain this feature.</p> <ol style="list-style-type: none"> 2. The Department will implement a plan and target completion for closing out open work orders, focusing on higher risk and order records. <p><u>Action Plan Owner:</u> Director, Operational Logistics</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. 07/31/2022 2. 06/30/2022

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response															
<ul style="list-style-type: none"> Equipment records were listed as requiring preventive maintenance but did not have WOs or evidence of actual maintenance activities. <p>The table below summarizes WOs aging:</p> <table border="1" data-bbox="100 440 781 659"> <thead> <tr> <th>Open Work Order Type</th> <th>31 to 90 Days</th> <th>91 to 180 Days</th> <th>> 180 Days</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>New Equipment Inspection</td> <td>860</td> <td>413</td> <td>792</td> <td>2,065</td> </tr> <tr> <td></td> <td>42%</td> <td>20%</td> <td>38%</td> <td>100%</td> </tr> </tbody> </table>	Open Work Order Type	31 to 90 Days	91 to 180 Days	> 180 Days	Total	New Equipment Inspection	860	413	792	2,065		42%	20%	38%	100%		
Open Work Order Type	31 to 90 Days	91 to 180 Days	> 180 Days	Total													
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	42%	20%	38%	100%													
<p>Risk Rating: Medium ●</p> <p>3. Enhance and Formalize Equipment Maintenance Service Request Processes and Monitoring Controls to Ensure Customer Satisfaction</p> <p>A formal standard process is not in place for Hospital and Ambulatory departments to request Biomed department equipment maintenance services. Clinical departments currently request services through phone calls or emails. This process does not ensure complete capture and tracking of equipment maintenance requests.</p> <p>Also, the priority levels are not set up in NUVOLO which would set standards to ensure maintenance is performed timely according to priority levels and meeting department expectations.</p>	<ol style="list-style-type: none"> 1. Implement a standard process for departments to request maintenance services. 2. Establish service quality measures for response time based on priority levels. 3. Implement system tools and reports to monitor results and make necessary periodic adjustments. 4. Consider adding view only accounts and assign them to department users to eliminate manual emails and streamline the inquiry process. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The Biomed Department will implement a call-center type customer service operation that will facilitate repair request from clinical departments. This Biomed customer service operation will also include a platform for clinical colleagues to submit repair request electronically and to check on repair status of medical equipment. 2. The Biomed Department will implement service response times that will be connected to the performance of the Biomed Customer Service operation and the Biomed Technician repair process. 															

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>This makes it difficult for establishing monitoring reports and controls. Specifically:</p> <ul style="list-style-type: none"> • Service dispatch priority levels and expected technician response times referenced in the Biomed work order process document ranges from immediate to 36 hours, but these performance goals are not currently set up nor measurable in NUVOLO. • Biomed technicians currently notify requesting departments of the repair status and completion through emails because departments do not have system access to review the job status in NUVOLO. 		<p>These response times will also be linked to the overall Biomed monthly metrics that are presented and reviewed in the monthly Biomed Subcommittee.</p> <ol style="list-style-type: none"> 3. The metrics that are established for the Biomed Customer Service operation and the Biomed Technician repair process will be used to monitor results that are charted and trended on a monthly basis. The results will be reviewed by the newly created Director of Clinical Engineering position. 4. We will coordinate with IR Support and software vendor to implement inquiry access only. <p><u>Action Plan Owners:</u></p> <ol style="list-style-type: none"> 1-3. Director, Operational Logistics 4. Director, Operational Logistics Assistant Vice President, IR Constituent Experience and Compliance, IR-AAIR Administration <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. Real Estate Evaluation to be completed by 5/31/22. Real Estate acquisition (move-in) by 9/30/22, and go-live by 12/31/2022. 2. Response time for Biomed technicians by 6/30/22. Response time for call center by 12/31/2022.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
		<p>3. Metrics for Biomed technicians by 6/30/22. Metrics for call center by 12/31/2022.</p> <p>4. 7/31/22</p>
<p>Risk Rating: Medium ●</p> <p>4. Capture Warranty and Equipment Maintenance Contracts Information in System to Ensure Compliance and Improve Equipment Maintenance Expense Management</p> <p>Equipment warranties or third-party contracted maintenance services information is currently not captured in NUVOLO to establish maintenance requirements and define ownership for maintenance during the warranty period or in compliance with service agreements. The warranty and third-party service contracts are difficult to obtain since the information may be included in a contract managed in the contracts management system, informally through Purchase orders in Jaegger or maintained by departments.</p> <p>When service requests are made and the work order is created, the warranty is not taken into consideration. This increases the risk of warranty violations or increased maintenance costs since the maintenance may have been covered by the manufacturer or other third party contract.</p> <p>Equipment obtained from an original equipment manufacturer (OEM) oftentimes comes with factory warranties, which can also be extended through subsequent service agreements or purchasing of third-party contracts.</p>	<ol style="list-style-type: none"> 1. Coordinate with NUVOLO to develop a plan for capturing equipment warranties and service contracts information inputting into NUVOLO. 2. Conduct an assessment to determine whether flagging can be done in existing systems and how information could be interfaced into NUVOLO for better tracking of requirements. 3. Formalize monitoring processes for ensuring proper capture and compliance with new equipment warranty requirements and other maintenance contract requirements. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The Biomed Department will implement a Biomedical Equipment Analyst position. The new position will be responsible for capturing warranty information and service contracts for the medical equipment categories that we have in our CMMS. This individual will report to the Biomed Customer Service Logistics Manager, and will have oversight of our Biomed Analytics and medical equipment service contract management. 2. The Biomed department will coordinate with Supply Chain Management and Information Resources to see what can be captured through the purchasing and contracts systems to ensure information for equipment under warranty or service agreements is captured and consistent across systems reducing the need for duplication of entry. 3. Alternatively, the Biomed Department will work with NUVOLO to implement a working function to capture equipment warranty information within the CMMS program.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>The information is not shared within Hospital Operational Logistics.</p>		<p>Action Plan Owners:</p> <ol style="list-style-type: none"> 1. Director, Operational Logistics 2. Director, Operational Logistics Assistant Vice President, IR Constituent Experience and Compliance, IR-AAIR Administration Director, Contracts Management 3. Director, Operational Logistics <p>Target Completion Dates:</p> <ol style="list-style-type: none"> 1. Implementing the position Completed, Hiring an analyst by 07/31/2022. 2. 7/31/2022 3. 08/31/2022
<p>Risk Rating: Medium ●</p> <p>5. Formally Document the Biomedical Equipment Maintenance Program at the Health System Level</p> <p>The University Hospital and Ambulatory operations include elements of the biomedical equipment maintenance life cycle. However, a formal documented maintenance program at the health system level is not yet in place to ensure operational compliance and effectiveness for overall deployment, maintenance and decommissioning of equipment. Specifically:</p>	<ol style="list-style-type: none"> 1. Consider developing an overarching equipment maintenance program policy document to ensure effective oversight across the hospital and ambulatory clinics. <p>Key program and policy elements would encompass business objectives, asset identification and classification, risk assessment process, maintenance types and frequency, service planning and scheduling, resources allocation and personnel training, service quality and performance measures monitoring.</p>	<p>Management Action Plans:</p> <ol style="list-style-type: none"> 1. We will coordinate to develop and update policies that would be similar across the University Hospital and Ambulatory clinics 2. The Biomed Department will implement steps to add or update new policies and procedures outlined in the recommendation: 3. The Ambulatory Operations will implement steps to add or update procedures similar to the hospital procedures to ensure consistent practices.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<ul style="list-style-type: none"> • Hospital standard operating procedures (SOPs) are not current and are in the process of being updated. • An overarching ambulatory policy designating responsibilities for ambulatory equipment maintenance does not exist. There have been circumstances in which Ambulatory Clinics have arranged their own equipment maintenance without going through the centralized biomedical equipment maintenance team. • Ambulatory SOPs for shifting from equipment maintenance contracted services to maintenance to be performed in-house are pending completion. <p>A comprehensive documented equipment maintenance program ensures consistency of processes and practices across University Hospital and Ambulatory operations including satellite clinics and offsite medical offices.</p>	<ol style="list-style-type: none"> 2. Update and finalize Hospital procedures to support the formal equipment maintenance program. 3. Develop Ambulatory procedures to support the formal equipment maintenance program. Communicate across the ambulatory areas. 	<p><u>Action Plan Owners:</u></p> <ol style="list-style-type: none"> 1. Associate Vice President & Chief Operating Officer - University Hospitals, Hospital Administration Associate Vice President & Chief Operating Officer, Ambulatory Services 2. Director, Operational Logistics 3. Associate Vice President & Chief Operating Officer, Ambulatory Services <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. Coordinate the updates with Ambulatory 5/31/2022. 2. Update, approval & finalize hospital policy and procedures by 09/30/2022 3. Update, approval & finalize ambulatory policy and procedures by 09/30/2022

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>6. Strengthen NUVOLO User Access Administration</p> <p>There is not a dedicated business owner responsible for monitoring NUVOLO user access. The IR ServiceNow team is responsible for setup of user groups without knowledge of appropriate access needed to grant users.</p> <p>This setup could result in granting conflicting access rights such as ability to edit critical input values or create and close their own transactions. A process to review user access is also not in place to ensure appropriate access.</p> <ul style="list-style-type: none"> • Four contractor accounts have user and manager, or user and admin privileges within the same user group. The accounts also have the same roles in multiple groups. • View only access is not available and all user accounts have the ability to make changes to the NUVOLO production database. • A process to monitor data entries is not in place. NUVOLO has a feature that enables tracking of changes; however, this feature has not been activated to monitor incorrect or unauthorized entries. 	<ol style="list-style-type: none"> 1. Establish a dedicated business administrative function within NUVOLO for more efficient monitoring. 2. Conduct a comprehensive review of all user account access including contractors to ensure users have appropriate access rights based on their roles and responsibilities. 3. Work with the software vendor to develop a process for obtaining system user and access reports directly from NUVOLO. 4. Implement view only user accounts that enable hospital and clinical departments to directly monitor progress and status of their maintenance requests. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The Biomed department will appoint a NUVOLO Administrator that has oversight over NUVOLO access submissions and approvals. The Biomed Department will work with our IR colleagues to ensure that all request for NUVOLO access either route through this individual or are submitted from this individual directly. 2. The Biomed Department will connect with our IR colleagues to review NUVOLO user access annually to ensure all inappropriate access levels are adjusted, or if necessary, revoked. 3. We will work with NUVOLO to determine the feasibility of creating user accounts directly in NUVOLO. 4. We will coordinate with IR Support and software vendor to implement inquiry access only in production or edit access in supplemental space. <p><u>Action Plan Owners:</u></p> <p>Director, Operational Logistics Assistant Vice President, IR Constituent Experience and Compliance, IR-AAIR Administration</p> <p><u>Target Completion Dates:</u></p> <p>1-4 07/1/2022</p>

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

<p>Risk Definition- The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.</p>	<p>Degree of Risk and Priority of Action</p>	
	<p>Priority</p>	<p>An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.</p>
	<p>High</p>	<p>A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.</p>
	<p>Medium</p>	<p>A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.</p>
	<p>Low</p>	<p>A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.</p>

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the above pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.