Office of Internal Audit

UT Southwestern Medical Center

The University of Texas Southwestern Medical Center
Vendor Recall Process
University Hospitals, Hospital Based Clinics and Ambulatory Clinics
Internal Audit Report 16:19

March 16, 2016

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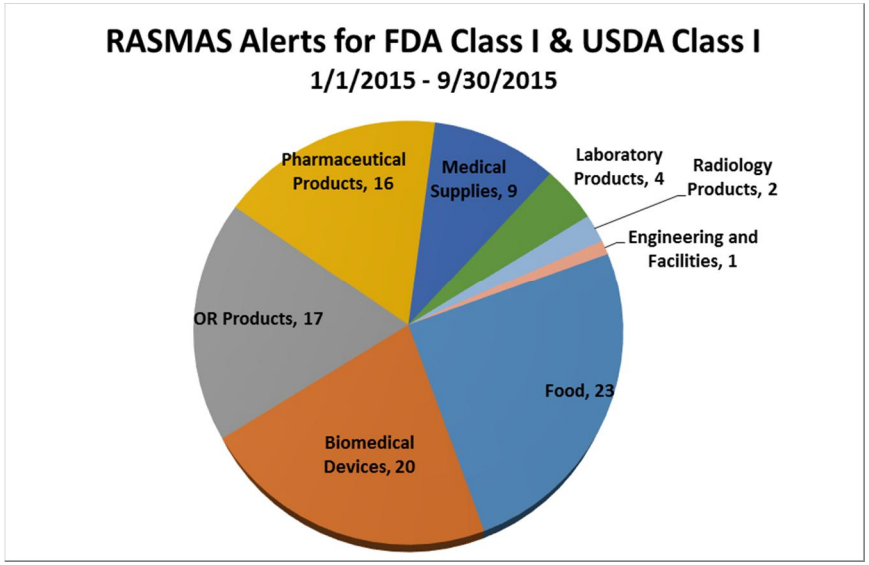
Executive Summary

Background

The University of Texas Southwestern Medical Center (UT Southwestern) must comply with US Food and Drug Administration (FDA) regulations related to the identification and removal of certain regulated products which have been identified as a potential risk to patients and/or employees. Regulated products include food, drugs, medical and radiological devices, cosmetics, and human biological products including blood and human tissue. There must be prompt and proper identification and recommended action when a product recall/alert is received to ensure patient safety and quality of care is not compromised.

The illustration provides a summary of the types of the 92 FDA Class 1 and USDA Class 1 recalls during the 9 month period from January 2015 through September 2015. A Class 1 recall is defined as a situation in which there is a reasonable probability that the use or exposure to a volatile product will cause serious adverse health consequences or death.



University Hospitals and Hospital Based Clinics

For University Hospitals and Hospital Based Clinics, the Risk and Safety Management Alert System (RASMAS) web-based system is used to coordinate the internal and external notification process for product and equipment recalls and/or alerts, along with their resolution and documentation. In addition to RASMAS, recall alerts for University Hospitals may also be obtained directly from the vendor, FDA alerts, or from ECRI (Medical Equipment consumer reporting service).

Coordinators are assigned by functional area to receive notifications applicable to their area. If actions on notifications are not recorded to the system by the Coordinators within 72 hours for Class 1 recalls, or five days for Class 2 and other recalls, the RASMAS Administrator will receive a follow up notice.

It is the responsibility of the assigned Coordinators to:

- Determine if the recalled product has been procured within the stated recall period
- Determine if the recalled product has been dispensed or otherwise used by a patient
- Isolate and coordinate the return of recalled product on hand with Purchasing
- Document results in the RASMAS application

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Ambulatory Clinics

Ambulatory clinics do not use the RASMAS service or any other system or tool for managing vendor recall notifications and resolution. Rather, the Office of Legal Affairs (Legal) distributes FDA recall/alert notifications via email on an ad hoc basis. Most Ambulatory administrative staff and team members are on the Legal department distribution list.

See Appendix B for overviews of the RASMAS and non-RASMAS product alert and vendor recall notification processes.

Scope and Objectives

The Office of Internal Audit has completed its Vendor Recall Process audit. This is a risk based audit and part of the fiscal year 2016 Audit Plan. The audit scope period included activities from January 1, 2015 to September 30, 2015. Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, substantive testing, and data analytics.

The primary objectives of the audit were to assess the adequacy and effectiveness of controls for management of vendor recalls. Specifically, to provide reasonable assurance of the following:

- Adequate processes and controls exist for notification, communication and coordination of vendor recall related activities.
- Reliability and integrity of RASMAS and other systems, and financial and operating information used in management of vendor recalls.
- Adequate procedures and controls are in place for identification of procurement and usage of recalled vendor devices and drugs.
- Effective processes and controls for sequestering medical device and drugs, returns and vendor credits.
- Adequate processes established to ensure compliance with U.S. Food and Drug Administration (FDA) requirements and institutional policies and procedures.

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

Overall, there are opportunities to strengthen governance and operational controls to minimize potential risks for product alerts and vendor recalls. A high risk issue exists at the institutional level related to the need for a more coordinated governance structure, including assigning overall accountability for the vendor recall processes and identifying requirements to ensure consistency in processes and documentation to support vendor recall actions.

A high risk issue exists for the Ambulatory (non-hospital based) clinics related to the need to establish a framework for managing product alerts and vendor recalls from notification processes through to final disposition. Currently, clinics each order their own products and have

Executive Summary

varying ways in which they may respond and manage vendor recalls, which increases the risks that the alerts and vendor recalls may not be appropriately addressed.

We did not find patient safety concerns for any recalls reviewed during the audit scope period.

Included in the table below is a summary of the observations noted, 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.

Priority (0)	High (2)	Medium (6)	Low (0)	Total (8)

Strengths identified during the audit include:

- All Level 1 FDA and USDA product recall notifications applicable to the audit testing scope period were reviewed and determined to have been appropriately and timely addressed.
- Current policies and procedures are in place for the handling of drug recalls and operating as designed.

The key improvement opportunities ranked as High and Medium risks are summarized below.

Institution

- **Establish an Institution Level Policy and Overarching Governance Plan for Vendor Recalls and Product Alerts –** A formal and coordinated governance effort is not in place for the management of product alerts and vendor recalls across the institution to ensure that vendor recalls are appropriately addressed and documentation is complete to support vendor recall actions.

University Hospitals and Hospital Based Clinics

- **Define and Monitor Performance for Handling Vendor Recalls and Product Alerts** –There are opportunities for improvement to management oversight and monitoring.

- **Track and Collect Vendor Credits Related to Product Recalls** – There is no formal process in place to notify University Hospitals Finance function when products are returned due to a vendor recall in order to follow up to ensure credits are received from vendors.

- **Ensure Patient Accounts are Appropriately Adjusted if Impacted By Vendor Recalls** - There is limited assurance in the process that all patient accounts impacted by vendor recalls are properly rebilled in accordance with Federal Medicare/Medicaid programs and third-party payor requirements.

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- **Improve RASMAS Documentation Standards** - RASMAS Coordinators do not provide adequate detail on the 'Closing Action Comment' section in RASMAS to determine if appropriate actions have been taken to address recalls.

Ambulatory Clinics

- **Establish a Formal Framework for Managing Vendor Recalls and Product Alerts in Ambulatory Clinics** – A formal and coordinated governance effort is not in place among the groups that share responsibility for the vendor recall process for Ambulatory services.

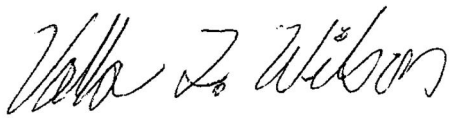
- **Establish Centralized Tracking of Recall Notifications and Actions** – Current broadcast email FDA product alerts and vendor recall notifications to decentralized Ambulatory clinic staff increases risks of incomplete or inappropriate actions in a timely manner.

- **Incorporate the Usage of the Procurement Function to Research and Track Products Subject to Recall** - Purchasing does not currently participate in the vendor recall process for Ambulatory clinics, but are in a unique position to perform certain steps in the process in a more efficient and effective manner.

Management has plans to address the issues identified in the report and in some cases have already implemented corrective actions. These responses, along with additional details for the key improvement opportunity listed above and other lower risk observations are listed in the Detailed Observations and Action Plans Matrix (Matrix) section of this report.

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

Sincerely,



Valla Wilson, Assistant Vice President for Internal Audit

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UT Southwestern Medical Center

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High 🟡 **1. Establish an Institution Level Policy and Overarching Governance for Vendor Recalls and Product Alerts** Responsibility for the administration of the institution's efforts regarding recalls and alerts is currently not addressed by an institutional policy. Accreditation and certification requirements of the Joint Commission have, to some degree, enabled the creation of a formal mechanism at University Hospitals and Hospital Based Clinics to monitor and resolve recalls and alerts. However, there are not procedures that reflect current practices, and an accountable person for oversight of the processes has not been defined. Ambulatory clinics, clinical research and other operations are also impacted by product alerts and vendor recalls, but they do not have a formal framework for managing the processes including documentation of actions. Purchasing methods may increase the risk for removal of product recalls. A lack of governance of the vendor recall and product alert processes across the institution increases the risk of ineffective processes which could impact patient safety and quality of care.	1. Establish an institution level policy and plan for oversight and governance of vendor recalls and product alerts. Include in the policy, the following areas: • Roles and responsibilities • Requirements for actions to be taken • Timelines for completion of actions • Reporting requirements and frequency 2. Establish overall accountability for Vendor Recalls. Materials Management can be in a unique position to serve as the primary point of contact as vendor recalls and product alerts are received as well as overall responsible party to coordinate with operational areas to ensure appropriate actions are taken. 3. As noted in observation #7, the Ambulatory clinics currently do not have a centralized repository for capturing and tracking vendor recalls and follow up actions taken. Consideration should be given to establishing a new structure as first priority. 4. Research operations were also noted as not having a centralized repository for vendor recalls and follow up actions taken, and should also be addressed as a high priority.	**Management Action Plans:** 1. An institution level policy for the product alert and vendor recall process will be drafted. 2. A formal governance structure for product alert and vendor recall management will be established under the Office of Materials Management. 3. Each business unit will develop Standard Operating Procedures (SOPs) for the management of vendor recalls in accordance with the established institutional policy. SOPs will be reviewed for consistency and consolidated at the institution level by the Office of Materials Management. 4. The contract with the recall management system (RASMAS) will be finalized in accordance with the new policy, governance structure and SOPs. **Action Plan Owners:** Assistant Vice President, Office of Materials Management Associate Vice President & Chief Financial Officer, University Hospitals Associate Vice President & Chief Operations Officer, University Hospitals Assistant Vice President, Ambulatory Clinical Operations and Training

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Target Completion Dates: 1. April 1, 2016 2. June 1, 2016 3. July 1, 2016 4. July 1, 2016

Detailed Observations and Action Plans Matrix

The following section contains observations related to University Hospitals operations, including hospital based clinics.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 🟡 **2. Define and Monitor Performance for Handling Vendor Recalls and Product Alerts** University Hospitals management oversight of product alerts and vendor recalls relies heavily on voluntary disclosure of all applicable and relevant information from staff, and may not provide sufficient guidance to staff on how to measure performance or the type of baseline information that should be reported for recalls and alerts. While management does have a mechanism in place, via staff meetings and other verbal updates, to stay abreast of activities and issues, a formal documented process is not followed. The following opportunities for improvement were noted: • University Hospitals and Hospital Based Clinics policy - *UHEC3-106: Product Alert and Recalls* - requires that 'Monthly Summary Reports' be submitted to the Environment of Care (EOC) Committee for tracking and information purposes. However, the feedback to the EOC Committee from the University Hospitals' RASMAS administrator is only a report of the number of recalls/alerts received for the month rather than overall updates on the status of active recalls. • *UHEC3-106* also requires a final resolution copy for recalls and alerts be sent to Clinical Safety files; however, no such reporting is done. • Key performance indicators (KPIs) have not been established to measure reasonable response time for each recall/alert classification level.	1. Establish key performance metrics for handling recalls and alerts and set up in RASMAS to develop a dashboard that management can use to easily monitor vendor recalls. 2. Define criteria to use to determine when a recall/alert can be considered closed by RASMAS Coordinators and documentation requirements. 3. Incorporate review of vendor recall and product alerts reporting into quarterly management operational reviews. Utilize reports available in RASMAS. 4. Provide guidance on what information to include in the 'Monthly Summary Reports' that are submitted to the EOC Committee.	**Management Action Plans:** 1. RASMAS dashboard reporting will be established to monitor product alerts and vendor recall activity, which will include key performance metrics. 2. Criteria will be developed to establish a closed loop process, starting with notification, through product disposition, to final credit from vendor. These criteria and how they must be documented within RASMAS will be incorporated in the SOPs. 3. Requirements for monthly and quarterly RASMAS management reporting and monitoring procedures will be incorporated into the SOPs. 4. Requirements for required EOC Committee reporting will be incorporated into the SOPs. **Action Plan Owners:** Assistant Vice President, Office of Materials Management Associate Vice President & Chief Financial Officer, University Hospitals Associate Vice President & Chief Operations Officer, University Hospitals **Target Completion Dates:** 1. July 1, 2016 2. July 1, 2016 3. July 1, 2016 4. August 1, 2016

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
• Management reports are available in RASMAS to monitor performance along certain benchmarks (e.g. Average Days to Close by Domain & Facility, or by Domain and Month) but are not currently generated for review by management. • Recall notifications may be marked as closed in the RASMAS system by responders, despite not having gone through the entire recall process (pick up of product by vendor, product destroyed, etc.). Expectations have not been set on when recalls should be recorded as closed in order to effectively monitor this performance measure. Without consistent monitoring of the documentation of actions taken on product alert and vendor recall notifications, there is a risk that missed, ineffective or untimely actions are not identified.		

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **3. Track and Collect Vendor Credits Related to Product Recalls** At present, there is no formal process in place for University Hospitals Finance to track credits due for products returned to the vendor due to recall. Specifically for purchases made in batches, a log is not used at the University Hospitals warehouse to track what, when, and how many recalled products were picked up by the vendor. • Queries are available from Enterprise Data Services (EDS) but are not currently used to generate a report for all pending Returns to Vendor (RTVs) for the month. The PeopleSoft AP module implementation is pending and would enhance controls for identifying vendor product returns and credits. Without proper monitoring of vendor returns, there is a risk that credits due to University Hospitals are not identified and collected; and a risk of reimbursement not being made back to the payors and non-compliance with Medicare rules.	1. Maintain a log at the University Hospitals warehouse that tracks products returned to vendor and includes evidence of when the product is picked up by the vendor or delivered to them. 2. Until the University Hospitals Accounts Payable (AP) module in PeopleSoft is implemented, coordinate with EDS staff to build a query that can generate a monthly report of all pending RTVs that can be used to monitor outstanding vendor credits.	**Management Action Plans:** 1. As noted in action plan for #2 above, criteria will be developed to establish a closed loop process, starting with notification, through product disposition, to final credit from vendor. A log for returns to vendor at the University Hospitals warehouse will be implemented as part of this closed loop process. 2. A pending RTV monthly report will be developed and generated monthly for monitoring of outstanding vendor credits. **Action Plan Owners:** Assistant Vice President, Office of Materials Management Associate Vice President & Chief Financial Officer, University Hospitals Associate Vice President & Chief Operations Officer, University Hospitals **Target Completion Dates:** 1. July 1, 2016 2. July 1, 2016

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **4. Ensure Patient Accounts are Appropriately Adjusted if Impacted by Vendor Recalls** A comprehensive formal process is not in place to ensure patient accounts are appropriately rebilled when associated with a vendor recall. Without an effective process for ensuring accounts are properly billed, there is a risk of non-compliance with Federal Medicare/Medicaid programs and third party payor requirements.	In coordination with the Office of Compliance, 1. Develop a standard process to ensure patient accounts are properly rebilled when associated with a vendor recall, including communications that should be in place from Finance to Patient Financial Services (PFS). 2. Develop a system edit that will flag credits in the AP Return to Vendor (RTV) report if related to a patient account.	**Management Action Plans:** 1. Process flow will be developed to incorporate all applicable areas required to be notified, including Surgical Services, HIM Coding, Billing, and Finance. 2. Once process flow has been finalized, Patient Financial Services (PFS) in cooperation with Compliance will educate all impacted areas on the updated processes. 3. As noted above, criteria will be developed to establish a closed loop process, starting with notification, through product disposition, to final credit from vendor. A system edit to flag credits in the RTV report if related to a patient account will be part of this closed loop process. **Action Plan Owners:** Associate Vice President, Revenue Cycle Operations **Target Completion Dates:** 1. Completed 2. July 1, 2016 3. July 1, 2016

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **5. Improve RASMAS Documentation Standards** There are no criteria or established standards for documenting the actions taken on notifications within RASMAS. The RASMAS Coordinators do not provide adequate detail on the 'Closing Action Comment' section in RASMAS, such as the specific appropriate corrective actions taken in response to applicable recalls. Without this relevant information, the system may not adequately demonstrate compliance to federal or state authorities; or capture a sufficient level of supporting detail in the case of future litigation from a vendor/patient.	Develop best practice language for recording closing action comments field of RASMAS (i.e. standardization of comments or actions taken in this field.), and enforce the management requirement that this field should not be left blank in RASMAS by Coordinators.	**Management Action Plans:** As noted above, each business unit will develop Standard Operating Procedures (SOPs) for the management of vendor recalls in accordance with the established institutional policy. The SOPs will establish best practice language and requirements for documentation of closing actions. **Action Plan Owners:** Assistant Vice President, Office of Materials Management Associate Vice President & Chief Financial Officer, University Hospitals Associate Vice President & Chief Operations Officer, University Hospitals **Target Completion Dates:** July 1, 2016

Detailed Observations and Action Plans Matrix

The following section contains observations related to Ambulatory Clinics

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High **6. Establish a Formal Framework for Managing Vendor Recalls and Product Alerts in Ambulatory Clinics** A formal and coordinated governance is not in place among the groups that share responsibility for the vendor recall process within UT Southwestern Ambulatory clinics. The following issues were noted with the current decentralized process: • There is not a responsible office, executive or administrative sponsor to manage and monitor these efforts to ensure proper product removals and patient notifications occur at all clinics. • Centralized policies and operating procedures are not in place for the vendor recall process for Ambulatory clinics so responsible personnel in the clinics may not be aware of the documentation and timeliness standards. • Need for improved coordination with PFS to ensure patient accounts are rebilled appropriately. Without standardized policies and procedures, practices may not be correct or consistently applied, increasing the risk to patient safety and health leading to increased reputational, regulatory and financial risks.	1. Create a work group of primary process stakeholders to address this issue. 2. Develop centralized policies and procedures for the vendor recall process for use by Ambulatory clinics. 3. Utilize Materials Management to track and monitor vendor recalls across the organization.	**Management Action Plans:** 1. As noted in action plan for Observation # 1 above, a formal governance process for product alert and vendor recall management will be established under the Office of Materials Management, to which Ambulatory clinics will be included. 2. In accordance with the institutional policy, a process will be established for Ambulatory clinics to track and monitor product alerts and vendor recalls. 3. In collaboration with Materials Management, Ambulatory clinics will develop departmental policies and procedures in accordance with the institutional policy for the management of product alerts and vendor recalls. **Action Plan Owners:** Assistant Vice President, Office of Materials Management Assistant Vice President, Ambulatory Clinical Operations and Training **Target Completion Dates:** 1. June 1, 2016 2. June 1, 2016 3. July 1, 2016

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **7. Establish Centralized Tracking of Recall Notifications and Actions** The Legal Department sends broadcast emails to a decentralized list of Ambulatory clinic staff contacts to communicate FDA vendor recalls and alert notifications. This process may not be effective to ensure actions are taken on all applicable recalls in a timely manner. Key observations include: • The distribution list has been informally compiled by Legal and may not be complete for all affected areas. For example, the School of Health Professions does not receive the email notifications. • Coordinators are not assigned to ensure that appropriate actions have been taken by the clinics for all recall/alert notifications. While in limited situations Ambulatory Clinical Services will monitor and follow up with the clinics on high-risk recalls/alerts, this process is not performed consistently for all notifications. • There are no standards for documentation to support the actions taken by the clinics on recall/alert notifications. Review at a sample of clinic locations found informal procedures for maintaining records and responding to recalls, with limited documentation supporting the actions taken and whether those actions were taken in a timely manner. Without centralized coordination and documentation of all recall/alert notifications, there is a risk that recalled products or equipment remains in use in the Ambulatory clinics.	Develop a centralized process, utilizing UTSW Materials Management, including: • Communication plan for receiving and responding to recalls and alerts. • Defining of performance metrics to track status of recalls. • Standards for documentation for efforts taken related to recalls. Leverage resources and share best-practices from the University Hospital as needed.	**Management Action Plans:** 1. In accordance with the institutional policy, a process will be established for Ambulatory clinics to track and monitor product alert and vendor recalls. 2. In collaboration with Materials Management, Ambulatory clinics will develop departmental policies and procedures in accordance with the institutional policy for the management of product alerts and vendor recalls. These policies and procedures will include the following: a. A representative assigned from each clinic to receive and respond to pertinent recall and alert notifications. b. A process in collaboration with Materials Management to verify purchase of products in question. c. Methods to monitor key performance indicators. **Action Plan Owners:** Assistant Vice President, Ambulatory Clinical Operations and Training Assistant Vice President, Office of Materials Management **Target Completion Dates** 1. May 1, 2016 2. June 1, 2016

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating Medium 🟡 **8. Use the Purchasing Function to Effectively and Efficiently Research and Track Products Subject to Recall** UTSW Purchasing (Office of Material Management) does not currently participate in the vendor recall process, but are in a unique position to perform certain steps in the process in a more efficient and effective manner. • Currently staff at the decentralized clinics will individually research all notifications to determine if the affected product is in their inventory. However, relatively few notifications will be identified as applicable to the clinic(s) via this process, while the duplicate review and verification of each FDA notification takes valuable time of administrative and direct care staff. Purchasing could perform a first level review of all recall/alert notifications to efficiently determine those notifications that apply to products actually purchased somewhere in the organization. • There is no formal process to direct vendor credit information to Office of Accounting when vendor recalls take place in Ambulatory clinics. The current process relies on the vendor to voluntarily initiate a credit if funds are due to UTSW for a recalled product.	Materials Management can serve as the primary point of contact and overall responsible party for ensuring appropriate actions are taken. This would include providing information to the key department coordinators on past purchasing history for items subject to recall.	**Management Action Plans:** 1. Ambulatory clinics' policies and procedures will include establishing a liaison in Materials Management who can verify purchase of products in question. 2. Ambulatory clinics policies and procedures will include a process, in collaboration with Materials Management, to notify Accounting, as appropriate, when a product is returned to vendor and a refund is due. **Action Plan Owners:** Assistant Vice President, Ambulatory Clinical Operations and Training Assistant Vice President, Office of Materials Management **Target Completion Dates:** 1. June 1, 2016 2. July 1, 2016

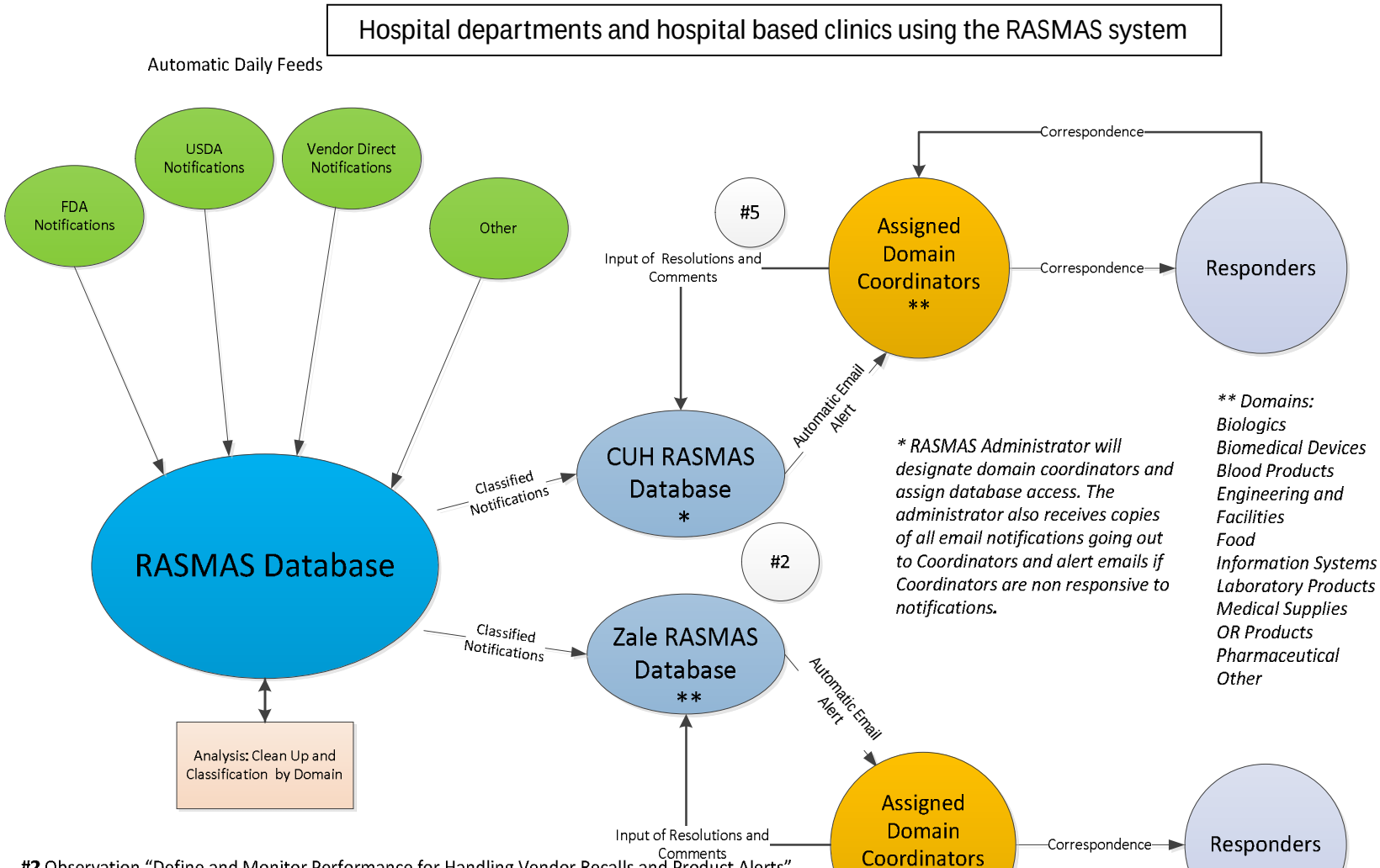
Appendix A – Risk Classifications and Definitions

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:

	Degree of Risk and Priority of Action	
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.	**Priority**	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.
	High	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.
	Medium	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 risk to a more desirable level.
	Low	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.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the subsequent 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.

Appendix B – Vendor Recall Notification Process Flow – Current State

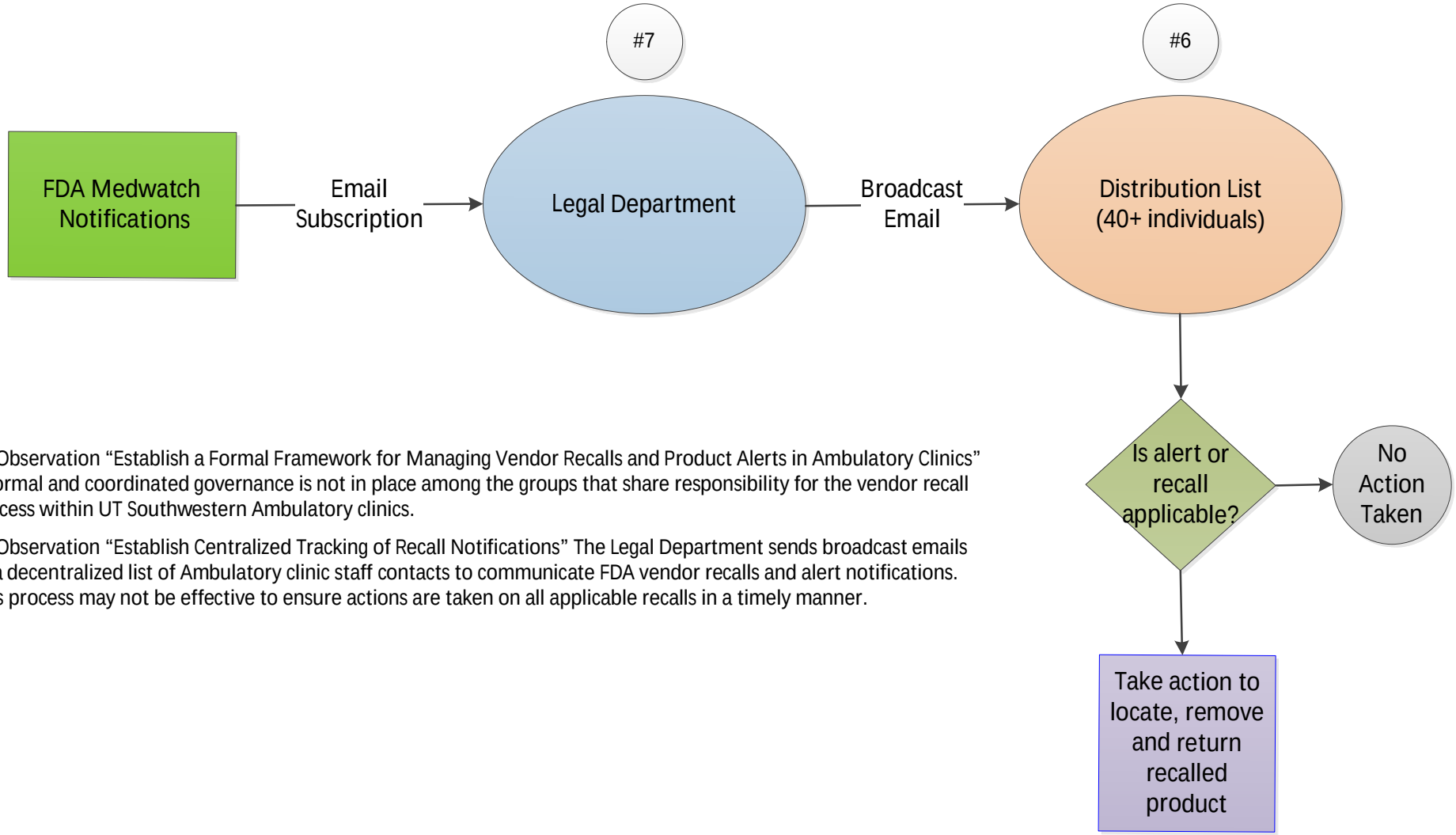


#2 Observation "Define and Monitor Performance for Handling Vendor Recalls and Product Alerts" University Hospitals management oversight of product alerts and vendor recalls relies heavily on voluntary disclosure of all applicable and relevant information from staff, and may not provide sufficient guidance to staff on how to measure performance or the type of baseline information that should be reported for recalls and alerts.

#5 Observation "Improve RASMAS Documentation Standards" There are not criteria or established standards for documenting the actions taken on notifications within RASMAS.

Appendix B – Vendor Recall Notification Process Flow – Current State

Process for departments not using the RASMAS system, including Ambulatory Clinics, Research operations and School of Health Professions



#6 Observation "Establish a Formal Framework for Managing Vendor Recalls and Product Alerts in Ambulatory Clinics" A formal and coordinated governance is not in place among the groups that share responsibility for the vendor recall process within UT Southwestern Ambulatory clinics.

#7 Observation "Establish Centralized Tracking of Recall Notifications" The Legal Department sends broadcast emails to a decentralized list of Ambulatory clinic staff contacts to communicate FDA vendor recalls and alert notifications. This process may not be effective to ensure actions are taken on all applicable recalls in a timely manner.