SAN DIEGO: AUDIT & MANAGEMENT ADVISORY SERVICES
0919

September 16, 2013

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Subject: ***Controlled Substances and Medication Waste Tracking and Reporting***
Audit & Management Advisory Services Project 2013-14

The final audit report for the above references audit is attached. We would like to thank all participants for their cooperation and assistance during the audit.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you to schedule a review of the corrective actions, and will advise you when the findings are closed.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them at this time. We also request that draft reports not be photocopied or otherwise redistributed.

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Attachment

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AUDIT & MANAGEMENT ADVISORY SERVICES

Controlled Substances and Medication Waste Tracking and Reporting
September 2013

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Project Number: 2013-14

Controlled Substances and Medication Waste Tracking and Reporting
Audit & Management Advisory Services Project 2013-14

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Controlled Substances and Medication Waste Tracking and Reporting
Audit & Management Advisory Services Project 2013-14

I. Background

Audit & Management Advisory Services (AMAS) completed a review of selected controlled substances and medication waste tracking and reporting processes as part of the approved internal audit plan for Fiscal Year 2012-13. This report summarizes the results of our review.

The University of California, San Diego Health System (UCSDHS) is comprised of the Hillcrest Medical Center, the home of the UC San Diego Stroke Center; and the San Diego Regional Burn Center; and the La Jolla Medical Center, which includes the Thornton Hospital, Moores Cancer Center, Shiley Eye Center, and Sulpizio Cardiovascular Center. In addition, the UCSDHS provides outpatient clinic services throughout San Diego County. Medication management procedures are critical to patient safety in an institution of the size and complexity of the UCSDHS.

According to an article in the April 2011 edition of the American Journal of Health-System Pharmacy, "All health care institutions that administer controlled substances are required to develop storage and distribution systems to minimize the risk of diversion. The Drug Enforcement Administration (DEA) estimated that prescription drug diversion in the United States is a $25 billion-a-year industry."[1]

In the fall of 2009, UCSD Regulatory Affairs self reported suspected drug diversion activity by a licensed Registered Nurse to the California Department of Public Health (CDPH) and a CDPH investigation was initiated. The investigation was completed in the winter of 2009, and deficiencies noted during that investigation required that UCSDHS design and implement process improvements.

Oversight for UCSDHS controlled substances has always been a collaborative effort between Pharmacy and Nursing managements and staff. Prior to the CDPH investigation, UCSDHS secured controlled substances using special vaults in most central Pharmacy locations; automated dispensing cabinets (ADC)[2] in a number of patient care areas, and physical access controls in units with medication cabinets. In response to the deficiencies identified by CDPH, a controlled substance vault was installed at the Hillcrest location, and Pharmacist oversight of medication orders was increased in selected areas, including the Emergency Department (ED) and Post Anesthesia Care Unit (PACU) by creating ADC profiles. In addition, management and staff education and training efforts were increased, controlled substance wasting

[1] American Journal of Health-System Pharmacy: *Compliance with Recommendations for Prevention and Detection of Controlled-substance Diversion in Hospitals*; April 15, 2011, 68:689-694.

[2] ADCs were either "profiled" or "non-profiled". A profiled ADC requires pharmacists to profile, screen, and approve medications for a patient before they are removed from the ADC.

procedures were improved, and additional personnel were assigned to complete monthly Pharmacy controlled substance audits.

II. Audit Objective, Scope, and Procedures

The objective of our review was to validate that management control procedures implemented in Fiscal Year 2009-10, or alternative controls were functioning as management intended to mitigate the risk of diversion and regulatory non-compliance.

We completed the following audit procedures to achieve the project objectives:

- Reviewed the UCSDHS response to CDPH review dated March 17, 2010;
- Summarized and evaluated the management control procedures implemented as corrective actions as of March 17, 2010 (***Attachment 1***);
- Reviewed Medical Center Policy (MCP) 321.1: *Controlled Substances: Distribution and Control;* and MCP 813.3:, *Hazardous Materials and Hazardous Waste Management*;
- Conducted interviews and inquiries of personnel in Environment, Health, and Safety; Environmental Services; Nursing; Nursing Education; Pharmacy; and Regulatory Affairs;
- Assessed Pharmacy controlled substance audit documentation and distribution procedures;
- Observed Pharmacy controlled substance distribution practices and reconciliation of anesthesia kits; and
- Reviewed pertinent components of the RN Annual Competency Review and new employee orientation presentations.

This scope of this audit was limited to validating that the management control procedures implemented in Fiscal Year 2009-10, or alternative control procedures that were being completed; and did not include an assessment of other related processes.

III. Conclusion

Based on the audit work performed, we concluded that management control procedures implemented in Fiscal Year 2009-10 or alternative procedures were in place, functioning as management intended, and were generally effective to help mitigate the risk of diversion and regulatory non-compliance.

While completing our review, AMAS identified additional opportunities for program improvements in reporting selected information to the hospital governing body for program monitoring; staff education; automating the reconciliation process, and the timeliness of reporting Pharmacy audit results.

IV. Observation and Management Corrective Actions

A. Improvements to the Controlled Substance Diversion Program

Although most management control procedures were implemented and working as designed, AMAS identified additional improvements to increase the effectiveness of the program.

1. Reports to the Medical Center Governing Body

   According to *42 C.F.R. §482.12,* the hospital must have an effective Governing Body that is legally responsible for the conduct of the hospital as an institution. Two Committees are considered to provide Governing Body level oversight for the UCSDHS: the Governance Advisory Council and the Medical Staff Executive Committee. Although reports on the Controlled Substance Diversion Program were periodically presented to the Nurse Executive Committee, overall Program information has not been reported to either Governing Body Committee or regularly to other Medical Center Committees to help ensure the effectiveness of the Program.

2. Continuing Education: Drug Wasting Procedures and Drug Diversion Behavior

   During our interviews with nurses to determine their familiarity with the drug wasting procedures, we determined that some nurses were uncertain of wasting procedures for drug delivery methods they did regularly encounter. We determined that the annual nursing update did not address drug wasting procedures by delivery method.

   Information on drug diversion behavioral signs is provided to nurses as part of the new employee orientation, and is included with Pharmacy controlled substance audit instructions. The annual nursing update does not include this topic, but it would likely raise awareness if included in annual training.

3. Automation of the Medication Reconciliation Process

   Controlled substance reconciliations are currently performed for all returned/wasted anesthesia kits and Pharmacy audits. Controlled substance orders, dispensed amount, waste, and returns are also documented for all ADC within the hospitals. UCSD has been working to refine the Epic Dispense Reconciliation Report to allow for automated reconciliation of controlled substances, however, there are currently challenges with the report providing an efficient record of waste and returned controlled substances. Therefore,

UCSDHS is continuing to work on refining the Epic Dispense Reconciliation Report to perform automated reconciliations.

4. Pharmacy Drug Diversion Audits

The Pharmacy's controlled substance audit process was initiated at the request of Nurse Managers or by generating a report that compared the controlled substances dispensed by ADC users (user) from one patient care area with other users from the same area. Users that were dispensed drug doses that were three standard deviations from the mean were selected for review. Compliance with UCSDHS policies and procedures was also evaluated during each review. The audit included a manual reconciliation of information from the order, drug administration entry, the ADC dispense report (the amount of drug dispensed), and documentation of the amount of drug wasted or returned for the user's 14 busiest days within the 30 day period.

The Pharmacy audit findings were provided to the Nursing Director, who forwarded the information to the supervising Nurse Manager for review and implementation of any required corrective action. Typically, the Nurse Manager completed his or her own review of the unusual cases in the report before discussing the audit findings with the user. When the Nurse Manager completed his or her review of the audit results, the general action taken was documented and the completed audit report was signed by the Nurse Manager, Pharmacy Director, and Nursing Director.

Nurse Managers indicated that the Pharmacy audit reports were not received timely in some cases, which made it more difficult to evaluate the audit findings and implement corrective actions.

Management Corrective Actions:

1. Pharmacy will identify Quality Assurance and Performance Improvement (QAPI) dashboard data points to summarize the Controlled Substance Diversion Program activities and results, and will present that information to the Governing Body via the Quality Council and Medical Staff Executive Committee.

2. Nursing Education will expand the annual nursing update education sessions and materials to include the wasting procedures for specific controlled substance delivery methods; and the behavioral signs associated with drug diversion. Pharmacy and Nursing Education will also re-educate physicians in clinical areas with a high risk of drug diversion. Other education activities will be conducted in fall 2013.

3. Pharmacy has continued to provide feedback to Epic regarding the usefulness of the Dispense Reconciliation Report to complete an automated reconciliation of controlled substances administration (order = dispensed – administered – wasted – returned amount). In the interim, Pharmacy continues to utilize its manual sample based reconciliation process, and has been refining processes around the Dispense Reconciliation Report.

4. Pharmacy has improved the timeliness of providing audit results to Nursing Directors and has included some historical audit information.

Controlled Substances and Medication Waste Tracking and Reporting
Audit & Management Advisory Services Project 2013-14
Status of Management Control Procedures Implemented as of March 17, 2010
Attachment 1

Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
1	The Hillcrest and Thornton Emergency Department (ED) discharge process was reviewed, revised and implemented.	High	●	-
2	All Pyxis machines at Hillcrest and Thornton EDs were converted to profile status, allowing prospective and retrospective review of all medication orders.	High	●	-
3	ED Nursing management will audit compliance on a daily basis to ensure that there is acknowledgement of patient receipt for all medications removed from the dispensing Pyxis. Further actions will be taken as necessary.	High	●	-
4	Pharmacists will review and profile all medications to be discharged with the patient.	High	●	-
5	Registered Nurses (RNs) will obtain patient acknowledgement of receipt of each medication provided to them at their time of discharge.	High	●	-
6	Medication orders for ED administration at Hillcrest or Thornton will print in a designated Pharmacy location (Hillcrest Central Pharmacy) for manual order entry.	Medium	●	-
7	Updated wasting procedures from UC San Diego Health System (UCSDHS) Policy (MCP) 321.1 and posted at Pyxis machines.	High	●	-
8	Pharmacy, ED nurses, and ED physicians are currently being educated on the revised processes related to discharge medications.	Low	-	-
9	Aggregated data for ED medication use patterns of high-risk drugs, boxed warning drugs, and other relevant data will be generated. A summary of this Quality Assurance and Performance Improvement (QAPI) focused activity will be presented quarterly to the Safe Medication Practices Committee and reported up the organization. The information will also be presented to the ED Clinical Service Chief and ED Nurse Director.	High	▲	-

[1] AMAS tested items identified as high or medium risk through the AMAS risk assessment. The status of Low risk items was documented if they were identified while completing the audit procedures performed.

● Control or other mitigating control is present.

■ Control is not present.

▲ Short-term control procedure, no longer in place because it was not intended for long-term implementation.

◆ Some controls are in place, additional controls are needed.

Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
10	Compliance with the waste container management corrective actions (MCAs) is audited by Environment Health & Safety (EH&S) via weekly Environment of Care Rounds and Regulatory Affairs via daily Tracer Rounds. If issues are identified, they are shared with the Governing Body.	Low	-	-
11	Large stand alone containers (trolleys) are kept in a locked room when not supervised by authorized personnel.	Low	-	-
12	All waste bins are exchanged when half full to prevent the removal of contents.	High	●	-
13	Waste bins are replaced five times per week with empty bins.	Medium	●	-
14	The Medical Center has defined the measures to be communicated and has prescribed the reporting committee structure for data flow.	High	◆	***Finding A.1***
15	The Governing Body is ensuring that routinely collected data and information about Licensed Nurses' practice variances and discrepancies with controlled substances via the proactive diversion audits and other sources is being reported to the Senior Leadership and Governing Body.	High	◆	***Finding A.1***
16	Trend reports will be presented regularly to key Medical Center Committees, including the Pharmacy & Therapeutics Committee, Nurse Executive Council, Senior Management Team, Quality Council and Medical Staff Executive Committee.	High	◆	***Finding A.1***
17	Controlled Substance Task Forces were established to develop, implement and monitor action plans based on Center for Medicare and Medicaid Services (CMS) validation survey findings.	Low	▲	-
18	The action plan, monitoring activities and reports being developed were presented to the Senior Executive Team on a weekly basis for their action and approval. Updates of the activities were being reported regularly to key Medical Center Committees, including Safe Medication Practices, Pharmacy & Therapeutics, Nurse Executive Council, Senior Management Team, Quality Council and Medical Staff Executive Committee.	Low	▲	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
19	A memo was sent by the Chief Medical Officer (CMO) to the Medical Directors of procedural areas and Operating Rooms regarding wastage of controlled drugs in their areas.	Low	▲	-
20	A memo was sent by the CMO to all Department Chairs, Medical Staff, Trainees, and Medical Directors regarding controlled substances reinforcing MCPs.	Low	▲	-
21	A review of the audit data for January 2010 was presented to the Controlled Substance Audit Process Subcommittee and Nurse Executive Committee to determine the effectiveness of the process.	Low	▲	-
22	The Controlled Substance Auditing Procedure and the March 2010 audit process will be evaluated for effectiveness.	Low	▲	-
23	MCP 813.3 was revised and updated to refer to the Controlled Substances policy for wasting to prevent discrepancies in the future, and to define authorized personnel and the communication expectations and training for those allowed in procedural areas after hours.	Low	●	-
24	Pyxis overrides are reviewed to assure that there is a valid order; and further reviewed for appropriateness.	High	●	-
25	Ambulatory clinic managers will continue to conduct controlled substance peer tracers, with an emphasis on wasting of controlled substances. The controlled Substance Peer Tracers will be conducted monthly, on a random basis.	High	●	-
26	The pain management education initiative will incorporate updates in appropriate use of controlled substances.	High	●	-
27	Staff were instructed to notify their supervisor if they identify an unsecured pharmaceutical and/or sharps container. Supervisors will contact Pharmacy for immediate removal.	High	●	-
28	Managers will discipline nurses deviating from these policies according to UCSD progressive discipline policies.	High	●	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
29	The procedural/OR/Post Anesthesia Care Unit (PACU)/ED nurse and a second licensed practitioner will complete the medication wasting and reconciliation process. This will be documented in the Pyxis Automated Dispensing Cabinet (ADC).	High	●	-
30	There was education provided to Nursing leadership at various Nursing Committees.	Low	▲	-
31	Expectations have been discussed at Nurse Manager meetings. In-services have been provided by Controlled Pharmacist Managers.	Low	-	-
32	The results and changes will be incorporated into education for staff/providers using a variety of communication methods including newsletters and bulletins.	Low	-	-
33	All inconsistent information was removed from patient care areas.	Low	-	-
34	The ambulatory clinics with controlled substances were identified as the Owen Clinic and the Urology Clinic. All staff in these clinics have been re-educated on the proper narcotic wasting procedures, and have signed attestations.	Low	-	-
35	Environment of Care Annual Training has been updated to be consistent with revised MCPs 321.1 and MCP 813.3.	Low	◆	***Finding A.2***
36	Wasting Controlled Drugs details.	High	●	-
37	Weekly department audits and daily Regulatory Affairs Tracer Audits include monitoring of pain assessment and re-assessment.	High	●	-
38	An educational program to support enhanced electronic quality variance reports (E-QVR) will be developed and provided to ED nurses and physicians with the intent to increase medication error reporting.	Medium	●	-
39	There was education during the RN Annual Competency Review regarding behaviors to watch for and the Controlled Substance Auditing Procedure.	Medium	■	***Finding A.2***
40	Wasting of controlled substances has been incorporated into the annual nursing education, and attestations are no longer required to be signed.	Medium	◆	***Finding A.2***

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
41	Nursing has begun training in pain management, assessment and reassessment as part of the Nursing Annual Update.	Medium	●	-
42	The temperature is charted on a UCSDHS Form, D-406, and the information is available on the top of the cart/refrigerator. Any deviations will be addressed per the existing MCP 321.9. The Manager of the Thornton and Hillcrest ORs is responsible for auditing to ensure that the MCP is followed.	Low	-	-
43	Refrigerators that contain medications or dietary items in patient care areas that are not already monitored via Pyxis or another centralized system will be migrated to the Awarepoint temperature monitoring system. The system utilizes temperatures recording radio frequency identification (RFID) temperature tags placed in Glycol to record temperatures continuously, and reports centrally on an internal Awarepoint website. Upper and lower ranges will be set by Facilities Engineering according to Pharmacy standards. The temperature will be maintained between 2.2 C (36 F) and 7.7 C (46 F).	Low	-	-
44	Each refrigerator is inspected daily using the correct thermometer.	Low	-	-
45	Implementing Computerized Physician Order Entry (CPOE) and Medication Administration (MAK) in the PACU.	High	●	-
46	Patient Controlled Analgesics (PCA) are no longer stocked in the PACU Pyxis.	High	●	-
47	All PCA must have an MD order and be provided by the Pharmacy.	High	●	-
48	A medication list is used for evaluation of the medication administration process for the Ambulatory Care clinics as part of the QAPI process.	Medium	●	-
49	Pyxis access is removed immediately when diversion is suspected. This process was reinforced during the education of Nursing leadership and Pharmacy.	High	●	-
50	All PACU orders are being profiled.	High	●	-
51	When the Epic Inpatient Pharmacy module is activated, the Pharmacy will enter all orders from	High	●	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
	the ED Web Charts print queue into the Epic Pharmacy System to populate the Pyxis profile.			
52	A pharmacist will review and validate medication orders for administration in the ED through a direct interface from the Epic ED module to Epic Inpatient Pharmacy module.	High	●	-
53	The Pharmacy is now reviewing 100% of orders for both Hillcrest and Thornton PACU and Same Day Surgery (SDS). New Pharmacy resources will be provided to review all medication orders in the PACU on a 24/7 basis.	High	●	-
54	The Hypothermia carts in the ORs have been brought into compliance, and are now monitored according to policy.	Low	-	-
55	All licensed ambulatory clinic areas that administer medications, including those with an ADC, will be incorporated into the prospective review process.	High	●	-
56	Pharmacist oversight of medication administration in the ambulatory clinics was redesigned.	High	●	-
57	The Pharmacy's role in medication oversight in the ED was redesigned.	High	●	-
58	Pharmacy audits include reconciliation of medications dispensed with physician orders.	High	●	
59	If no reasonable explanation is found for a deviation based upon the initial evaluation of the Controlled Substance Standard Deviation Report sorted by location and medication, an intensive review will be performed by Pharmacy.	High	●	-
60	Pharmacy is prospectively reviewing all medications that clinics request for potential use. Pharmacy will seek clinical justification from clinic managers and/or providers when requested drugs are deemed to be inappropriate for the scope of the clinical services provided in each clinic. The final outcome will be documented and maintained in the Pharmacy.	High	●	-
61	A process was defined for oversight and monitoring of controlled substances.	High	●	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
62	On a monthly basis, Pyxis activity reports are run and evaluated with an emphasis on non-profiled areas. A sample of medications will be selected for more in-depth review.	High	●	-
63	UCSDHS identifies discrepancies in the dispensing and administration of controlled substances.	High	◆	***Findings A.3 & A.4***
64	Pharmacy in conjunction with Nursing established a collaborative procedure to audit controlled substances effectively.	High	●	-
65	All pharmaceutical and sharps containers (bins) are exchanged while under the supervision of licensed Pharmacists.	High	▲	-
66	Controlled substance wasting procedures were developed for non-profiled Pyxis areas.	High	●	-
67	Any authorized staff member with a standard deviation in two or three consecutive months will have an intensive review performed by Pharmacy.	High	●	-
68	Any authorized staff member with a standard deviation of three or greater will have an intensive review from Pharmacy.	High	●	-
69	An initial evaluation of the standard deviations data will be done. If a reasonable explanation for the deviations is found, no audit will be conducted.	Medium	●	-
70	A report is now in production that lists all medications administered in clinics.	Medium	●	-
71	For non-profiled Pyxis areas, the pharmacy will conduct retrospective reviews.	Medium	▲	-
72	Pharmacy will review the appropriateness of an order. RNs cannot access medications without release of an order from Pharmacy, resulting in no overrides.	Medium	●	-
73	The PRM list will be reviewed and approved by the Senior Management Team at least annually.	Medium	▲	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
74	Periodic review of discharge Pyxis utilization and random observations of the process will be presented to the appropriate committees for review and further action. Committees include ED Leadership and Pharmacy and Therapeutics.	Medium	●	-
75	Quarterly summary reports will go to the Senior Management Team, Pharmacy and Therapeutics, Quality Counsel, and Medical Staff Executive Committee.	Medium	▲	-
76	Pharmacists were redistributed from existing staff for immediate 24/7 review of all orders.	Low	●	-
77	New Pharmacy resources will be provided to review all medication orders in the ED 24/7. Recruitment of new Pharmacists will begin on 4/15/2010.	Low	●	-
78	All pharmacists reviewed the MCP changes and signed the Controlled Drug Distribution and Control Policy update.	Low	-	-
79	A best practice model literature search was conducted to determine ways other organizations have minimized the timeframe between actual diversion and discovery.	Low	-	-
80	Licensed clinics in Medical Offices North and South are currently monitored 24/7 through Central Dispatch with an appropriate out of range notification and escalation process in place.	Low	-	-
81	Targeted, intensive audits were conducted by the Controlled Substance Audit Process Task Force.	Low	-	-
82	Practitioners who handle controlled substances must sign the Controlled Drug Distribution and Control Policy update before caring for patients. (Superseded by class)	Low	-	-
83	Actions will be implemented and evaluated for effectiveness using the measurement processes described above.	Low	-	-
84	The Nursing Director in consultation with the Pharmacy Director determines disciplinary actions that will be taken, up to and including suspension and termination.	High	●	-
85	Review of electronic Medication Administration Record (MAR) reports is performed, including MAK overrides.	High	●	-

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Line	Management Control Procedure	Risk Assessment[1]	Control Present	Report Reference
86	The Medical Center's corrective action, discharge, and discipline procedure will be implemented related to narcotic discrepancies and accountability for licensed staff.	High	●	-
87	UCSDHS revised the Controlled Substance Auditing Procedure to ensure formal oversight of controlled substance audits.	High	●	-
88	The Pharmacy Director reviews and signs off the completed audits by the Controlled Substance Audit Pharmacists to ensure that the intensive review of documentation is complete, clear and actionable. Additional details are also provided on this process to the Nurse Director.	High	●	-
89	Leadership will oversee the program and make determinations of the number of distinct improvement projects that will be conducted annually and provide adequate staffing for fulfillment of the program scope and outcomes.	Medium	▲	-
90	Medication administration (Medpass) audits will be instituted as a joint program between Regulatory Affairs, Pharmacy, and Nursing. The audits will initially focus on patients on pain medication, and controlled substances, especially in non-profiled areas. Security of medications from receipt to wastage will be evaluated.	Medium	●	-
91	The contrast warmer was reviewed and determined to not be necessary for the storage of contrast media. The warmer has been removed and contrast media is now stored in locked areas in accordance with policy. Other Radiology areas were reviewed to ensure no other warmers were in use.	Low	-	-
92	All waste bins are secured and/or placed into locked holders.	High	●	-

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