

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

SOP: HRP 02.05

Approval Date: 1/10/08

AUDITING THE INVESTIGATIONAL DRUG SERVICE (IDS)

OBJECTIVE:

- To ensure that the operations of the Investigational Drug Service comply with VA and other federal regulations as well as VAMHCS and other local standards.
- To ensure that the operations of the Investigational Drug Service are routinely monitored by Research Service staff.
- To ensure that remedial action is taken for any shortfalls found or, if the error cannot be corrected, to make changes in procedures to prevent problems in future subjects/studies.
- To document internal quality assurance activities regarding the Investigational Drug Service.

BACKGROUND / SCOPE:

The VAMHCS Research Service and the VAMHCS Pharmacy Service have formal policies in place for receipt, security, dispensing, accountability, and disposal of investigational entities. The Research Service has designated its Office of Research Compliance (ORC) to oversee quality management activities of the VAMHCS Investigational Drug Service (IDS). Due to limited resources, the ORC will focus its attention on matters that directly impact human participants' safety and regulatory compliance. In this plan, a routine audit of the Investigational Drug Service will occur at least on a biannual basis. Additional audits will be triggered by specific circumstances (SOP# HRP02.02, "Audit Triggers"). The ORC is not responsible for quality management activities of the Pharmacy Service as a whole.

RESPONSIBILITIES:

The Investigational Drug Pharmacist (IDP) is responsible for:

- collaborating with the VA Pharmacy Service in establishing internal policies and procedures governing the Investigational Drug Service and for having the policies approved through normal VAMHCS channels;
- complying with institutional, state and federal policies and regulations regarding the handling of investigational entities;

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- keeping accurate records of receipt, dispensing and disposal of study entities;
- ensuring that satellite sites for studies conducted through the Investigational Drug Service (IDS) comply with all applicable policies and procedures;
- complying with applicable policies when the IDS is itself a satellite site;
- ensuring that his/her staff complies with internal policies and procedures, VAMHCS SOPs, GCPs, and other applicable policies;
- facilitating the efforts of staff in this process.

The Research Compliance Specialist (RCS) is responsible for:

- auditing the activities of the VAMHCS Investigational Drug Service according to the procedures outlined in this SOP;
- discussing audit findings with the Investigational Pharmacist and collaborating on a resolution plan as needed;
- reporting her/his findings to the Research Compliance Officer (RCO).

DOCUMENTS:

- (Appendix 1) “Study Subject Worksheet”
- (Appendix 2) “Pharmacy Audit Form A: Investigational Drug Dispensing Tool”
- (Appendix 3) Companion Tool for Pharmacy Audit Form A
- (Appendix 4) “Pharmacy Audit Form B: Investigational Drug Log Tool”
- (Appendix 5) Companion Tool for Pharmacy Audit Form B
- (Appendix 6) “Pharmacy Audit Form C: Investigational Drug Service Audit Report”
- (Appendix 7) VAMHCS Investigational Drug Service Drug Log

SEE ALSO:

Research Service SOP Audit Triggers (HRP 02.02)
Research Service SOPs and Guidelines on related topics

PROCEDURE:

1. Audit triggers are identified and acted upon according to SOP# HRP 02.02, “Audit Triggers”.
2. Routine (scheduled) spot audit
 - 2.1. As time and staffing allows, the Office of Research Compliance (ORC) may perform one or more audits per year (but at least biannually) on the Investigational Drug Service.

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- 2.2. The audit will usually be performed by an RCS, but may also be done by the RCO, delegates of the IRB, or other appropriate agents.
- 2.3. The auditor will notify the Investigational Pharmacist that an audit is due and will arrange for a site visit. Although the auditor will work independently during the audit, it is essential for the Investigational Pharmacist to be available to answer questions during the audit and to attend the exit interview.
- 2.4. The auditor will obtain a list of active studies administered by the Investigational Drug Service. The auditor will randomly select 3-5 studies depending on the total number of studies, but will audit more if necessary. The auditor will try to include VA Cooperative Studies, industry studies, Greenebaum Cancer Center studies, and investigator-initiated studies in his/her sampling of studies to be audited.
- 2.5. The Research Service may adjust the audits based on the type & situation of audit being conducted.
- 2.6. The auditor will use versions of the forms and procedures outlined in #4.3 below.
- 2.7. At the conclusion of the audit, an exit interview will be held with the Investigational Pharmacist to review and clarify audit observations, answer questions, and collect feedback on the audit process.
- 2.8. An audit report will be completed (Appendix 6). If necessary, resolution plans will be negotiated with the Investigational Pharmacist and documented on the "Investigational Drug Service Audit Report".
- 2.9. The resolution plan should be completed within the following two (2) weeks. The auditor will conduct follow-up assessments as needed until the plan is completed and signed off by the RCO/RCS.
- 2.10. Final Reports (see #5 below) will go to the Investigational Pharmacist, the RCO and, through the RCO, the R&D Committee, the ACOS/R&D, EPIC, the IRB, and regulatory agencies if necessary. The Chief, Pharmacy Service is also made aware of audit results. The Investigational Pharmacist and the Chief, Pharmacy Service will be notified in writing if there is a possibility of inspection by regulatory authorities. See item #5 below for details about the Final Audit Report.
- 2.11. Original audit sheets, notes and reports are filed in the ORC.

3. For-cause audits

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- 3.1. For-cause audits can be generated by the findings of routine audits (e.g. the audit finds cause for deeper scrutiny and problem-solving) or by audit triggers described in SOP # 02.02, “Audit Triggers”.
- 3.2. There is a possibility that the audit can expand beyond the initial trigger if findings reveal deeper or additional areas of concern.
- 3.3. The RCS, the RCO, or other appropriate person performs the audit.
- 3.4. Little prior notice is given to the Investigational Pharmacist.
- 3.5. Enrollment of new subjects to some or all studies administered by the Investigational Drug Service may be halted pending the conclusion of the audit.
- 3.6. The auditor first assesses the basic problem/complaint. It is possible that an exhaustive root cause analysis will not be necessary if the Investigational Pharmacist has already identified and activated remedial actions, if the problem/complaint does not appear to be related to the Pharmacy Service itself, if the problem/complaint does not appear to be institutionally related, if the problem/complaint does not appear based in fact, or other reasons. The auditor must report to the RCO the reasons why a full audit is not performed.
- 3.7. If there appears to be reason for a thorough audit, an audit plan is specifically designed to examine the area of concern and a root cause analysis is performed. This audit plan may necessitate the development of specific audit tools. VAMHCS Risk Management or Performance Improvement may be included as an auditor or as a second prong in the audit approach.
- 3.8. Up to 100% of charts may be subject to audit.
- 3.9. The RCS may conduct study audits, regulatory document audits, inspections of internal policies and procedures and SOPs, and audits of compliance with Research Service/VAMHCS policies, procedures and SOPs. The Research Service reserves the right to audit other documents as necessary for the type & situation of audit being conducted.
- 3.10. At the conclusion of the audit, an exit interview will be held with the Investigational Pharmacist to review and clarify audit observations, answer questions, and collect feedback on the audit process. If necessary, resolution plans will be negotiated with the Investigational Pharmacist and documented on the “Investigational Drug Service Audit Report”.

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- 3.11. An audit report will be completed (Appendix 6). If necessary, resolution plans will be negotiated with the Investigational Pharmacist and documented on the “Investigational Drug Service Audit Report”.
- 3.12. The Resolution Plan should be completed within the following two (2) weeks. The RCS will conduct follow-up assessments as needed until the Plan is signed off.
- 3.13. Final Reports (see #5 below) will go to the Investigational Pharmacist, the RCO and, through the RCO, the R&D Committee, the ACOS/R&D, EPIC, the IRB, and regulatory agencies if necessary. The Chief, Pharmacy Service is also made aware of audit results. The Investigational Pharmacist and the Chief, Pharmacy Service will be notified in writing if there is a possibility of inspection by regulatory authorities. See item #5 below for details about the Final Audit Report.
- 3.14. Original audit sheets, notes and reports are filed in the ORC.
4. The audit process is outlined below. The process is similar whether for a “routine audit” or a “for cause audit”.
- 4.1. The RCS obtains selected charts from the Investigational Pharmacist and initiates the audit using pharmacy audit tools and worksheet (see Appendix 1-6).
- 4.2. If a document is misfiled within the pharmacy or takes more than several minutes of the auditor’s time to locate within the pharmacy file, the auditor may list it as missing. If a particular document needs to be filed in an unusual place, the Investigational Pharmacist places a memo in the pharmacy file stating where the document may be found.
- 4.3. The RCS examines the pharmacy chart(s) and completes the audit tools in the following order:
- i. Part 1 of “Pharmacy Audit Form C: Investigational Drug Service Audit Report” (this section contains information on the studies audited)
 - ii. “Study Subject Worksheet” (collects data needed to complete Form A)
 - iii. “Pharmacy Audit Form A: Investigational Drug Dispensing Tool” (contains information on the pharmacy files)
 - iv. “Pharmacy Audit Form B: Investigational Drug Log Tool” (specifically audits the drug log)
 - v. Parts 2-3 of the “Pharmacy Audit Form C: Investigational Drug Service Audit Report” (summarizes the findings)
- 4.4. Each form has a companion guide which may be used by the auditor if necessary for guidance on completing the forms.

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- 4.5. If a problem is discovered, it is noted in the comments sections or in Part 3 of Form C.
- 4.6. The auditor retains the original audit forms. Copies may be given to the Investigational Pharmacist. The auditor gives the pharmacist a copy of the Audit Report and schedules a follow-up review of resolutions for approximately two weeks from the date the report is given to the Investigational Pharmacist.
5. Formal reports will be developed as follows:
 - 5.1. Observations will be listed in the audit report (Part 3 of Form C) in order of decreasing significance.
 - 5.2. The audit report will also describe any resolution plan(s) and the compliance with or results of implementation of those plans.
 - 5.3. The draft report and all other audit documentation will be forwarded to the RCO for review and approval.
 - 5.4. The final audit report will be presented to the R&D Committee, the ACOS/R&D, EPIC, the IRB, and regulatory agencies if necessary. The Chief, Pharmacy Service is also made aware of audit results with the addition of comments from the oversight committees. If applicable, the PI will be asked to respond to issues raised by the committees.
 - 5.5. Follow-up discussions, documentation, reports and letters will occur as necessary until the issue(s) are resolved to the greatest extent possible.
 - 5.6. The Full Audit report will summarize all of these developments and will be forwarded to the entities listed in 2.10 and 3.13 above.
 - 5.7. If necessary, regulatory agencies such as ORO, OHRP, the FDA, etc., will be notified. The PI and the Division Chair will be notified in writing if regulatory authorities have been notified.

REFERENCES

Pharmacy assessment tools from the Center on Assessment and Compliance Help (COACH)

APPROVAL

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This SOP entitled “Auditing the Investigational Drug Service” has been approved by the Medical Center Director, effective 1/10/08.

Appendix 1

“Study Subject Worksheet”

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AUDITOR: _____

DATE: _____

STUDY: _____

SUBJECT ID:	Y/N/NA									
1. There is a signed informed consent form, a signed signature page OR a log signed by the pharmacist who visualized the signed ICF:										
2. The log states that the ICF was signed by the subject/subject's representative:										
3. The log states that there was a witness to the subject's signature:										
4. The log states that there was an informed consent form with the individual who conducted the consent process' signature present for all enrolled subjects in the investigational pharmacy?										
5. OP prescription only: Name of authorized practitioner signing the prescription (signing practitioners of IP and OP orders are automatically identified in CPRS)										
6. Number of "N" responses for Question Numbers 1-5 =										
COMMENTS										

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Appendix 2

“Pharmacy Audit Form A: Investigational Drug Dispensing Tool”

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AUDITOR: _____ DATE: _____

STUDY (see names of studies on Form C):	A Y/N/NA	B Y/N/NA	C Y/N/NA	D Y/N/NA	E Y/N/NA	F Y/N/NA
1. Does the VA Pharmacy Service have a copy of the approved protocol in the investigational pharmacy or one is available on-line?						
2. IRB Approval letter						
3. VA Form 10-1223 (HSS Approval)						
4. R&D Approval letter						
5. Investigators Brochure (for investigational drugs only) (in the pharmacy or available on-line)						
6. "Consent Form Verification" log with the investigational pharmacists' initials or signature indicating that the signed subject consent form was reviewed prior to dispensing the study drug and that all signatures were present?						
7. Does the VA Pharmacy Service have a completed, correct VA Form 10-9012 for the research study for all study drugs (including approved drugs)?						
8. Number of "N" responses for Question Numbers 1-7 =						
COMMENTS:						

ADDENDUM FOR VA COOPERATIVE STUDIES

Auditing the Investigational Drug Service (HRP 02.05)
Prior versions: 1.0 (10/04)

Version 2.0

Review due: 01/08

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STUDY:	A Y/N/NA	B Y/N/NA	C Y/N/NA	D Y/N/NA	E Y/N/NA	F Y/N/NA
9. FDA Form 1571 the Investigational New Drug Application:						
10. Copy of the IND letter from the FDA:						
11. FDA Form 1573 Statement of the Investigator for the participating investigator from the Cooperative Studies Program Clinical Research Pharmacy:						
12. Number of "N" responses for Question Numbers 10-12 =						
COMMENTS:						

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Summary of Investigational Drug Dispensing Tool for Evaluated Research Studies

Study	Number of "N" responses for Questions 1-7:	Number of "N" responses for Questions 10-12:
A		
B		
C		
D		
E		
F		

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Appendix 3: COMPANION TOOL for Pharmacy Audit Form A

DIRECTIONS: Both paper and electronic documentation within the investigational pharmacy may be used to answer the following questions. Use a new “Investigational Drug Dispensing” tool for each evaluated pharmacy file. To complete this tool, evaluate all research subjects enrolled in the pharmacy file. Use the “Study Subject Worksheet” to obtain data for individual subjects.

	Guidance / Instructions
1. Does the VA Pharmacy Service have a copy of the approved protocol in the investigational pharmacy?	It is OK to use BRAAN or electronic copy rather than a hard copy; state whether this is the case.
2. IRB Approval letter	Document the date on Form A. No consent form should be signed/dated prior to IRB and R&D approval.
3. VA Form 10-1223	This is the HSS Approval letter. Document the date on Form A. No consent form should be signed/dated prior to IRB and R&D approval.
4. R&D Approval letter	Document the date on Form A. No consent form should be signed/dated prior to IRB and R&D approval.
5. Investigators Brochure	For unapproved drugs only. It is OK to use BRAAN or electronic copy rather than a hard copy; state whether this is the case.
6. “Consent Form Verification” log with the investigational pharmacists’ initials or signature indicating that the signed subject consent form was reviewed prior to dispensing the study drug and that all signatures were present?	The VA Pharmacy Service uses a log to ensure that a pharmacist who is responsible for dispensing the investigational drug personally viewed the subject’s informed consent form prior to dispensing the drug, as well as whether all required signatures are present (see “Consent Form Verification process” attached).
7. Does the VA Pharmacy Service have a completed VA Form 10-9012 for the research study?	Must be complete and correct in all fields; (as of _/07), must have passed HSS. Must have one for each study drug (even if approved drug(s))

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ADDENDUM FOR VA COOPERATIVE STUDIES ONLY

	Guidance / Instructions
8. FDA Form 1571 the Investigational New Drug Application:	For studies involving new drugs only
9. Copy of the IND letter from the FDA:	For studies involving new drugs only
10. FDA Form 1573 Statement of the Investigator for the participating investigator from the Cooperative Studies Program Clinical Research Pharmacy:	For all studies

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Appendix 4

“Pharmacy Audit Form B: Investigational Drug Log Tool”

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AUDITOR: _____ DATE: _____

STUDY (see names of studies on Form C):	A Y/N/NA	B Y/N/NA	C Y/N/NA	D Y/N/NA	E Y/N/NA	F Y/N/NA
What is the number of investigational study drugs identified in the research protocol?	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____
How many are commercially available?	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____	Nmbr _____
1. Is an investigational drug log present in the VA Investigational Pharmacy for each study drug?						
2. Does the investigational drug log document the <u>name of the study drug</u> ?						
3. Does the investigational drug log document <u>the name of the manufacturer or other source</u> of the study drug?						
4. Does the investigational drug log document <u>the date of the receipt</u> of the study drug?						
5. Does the investigational drug log document the <u>quantity received</u> of the study drug?						
6. Does the investigational drug log document the <u>expiration date or "retest date"</u> of the study drug?						

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7. Does the investigational drug log document the <u>control number</u> of the study drug?						
8. Does the investigational drug log document the date the research protocol was approved (<u>date of IRB approval AND R&D approval</u>)?						
9. Does the investigational drug log document <u>the name of the authorized practitioner signing the study drug prescription</u> ? See Companion Tool.						
10. Does the investigational drug log document the <u>name of the patient</u> receiving the prescription?						
11. Does the investigational drug log document the <u>serial number of the prescription</u> ? (NA if drug is processed through CPRS or VISTA; indicate which.)						
12. Does the investigational drug log document the <u>quantity of study drug dispensed</u> ?						
13. Does the investigational drug log document <u>the balance of study drug</u> remaining after the study drug was dispensed (transaction)?						
14. Signed initials of the dispensing pharmacist						

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15. Balance adds up						
Totals						
How many of Question Numbers 3-14 were answered "N"?						
COMMENTS:						

ADDENDUM FOR DRUG DISPOSAL OR DESTRUCTION

STUDY:	A Y/N/NA	B Y/N/NA	C Y/N/NA	D Y/N/NA	E Y/N/NA	F Y/N/NA
16. Date of termination of use of drug:						
17. Reason for termination of use of drug:						
18. Quantity remaining:						
19. Disposal method:						
20. Number of "N" responses for Question Numbers 15-18 =						
COMMENTS:						

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Summary of Investigational Drug Log Tool for Evaluated Research Studies

Study	Number of "N" responses for Questions 3-14:	Number of "N" responses for Questions 16-19:
A		
B		
C		
D		
E		
F		

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Appendix 5: COMPANION TOOL for Pharmacy Audit Form B

DIRECTIONS: Numerous types of paper and electronic documentation within the investigational pharmacy may be used to answer the following questions. Examples of some types of acceptable documentation, but not all, are included. All of the information does not have to be on a single form. Use "Pharmacy Report C..." to identify studies A-F, and then use it to complete this Tool B for each evaluated pharmacy file. Please mark "Y" for Yes and "N" for No to answer the following questions. For questions not requiring a "Y" or "N" response, fill in the appropriate blank. Complete this tool on three (3) different pharmacy files to obtain a summary score.

	Guidance / Instructions
What is the number of investigational study drugs identified in the research protocol?	If a research protocol involves more than one study drug, each study drug will be evaluated.
How many are commercially available?	
1. Is an investigational drug log present in the VA Investigational Pharmacy?	Investigational drug logs may be paper or electronic. They may be the Sponsor's or the VAMHCS'. Sometimes two or three forms may be used. There should be a log for each study drug, including approved drugs if there is a study supply of these drugs (as opposed to general stores). Make a note if the latter applies (general stores).
2. Does the investigational drug log document the <u>name of the study drug?</u>	May be generic or chemical names be used. May need a memo to file for triple-blind studies
3. Does the investigational drug log document <u>the name of the manufacturer or other source</u> of the study drug?	If the protocol is located in the pharmacy, and the protocol contains the name of the manufacturer of the drug, the protocol is sufficient. If a shipping invoice is obtained that contains the name of the manufacturer, the shipping invoice is sufficient. NCI, kits, etc often do not give this info. State if this applies.

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4. Does the investigational drug log document <u>the date of the receipt</u> of the study drug?	May not be possible for “hospital supply” studies.
5. Does the investigational drug log document the <u>quantity received</u> of the study drug?	
6. Does the investigational drug log document the <u>expiration date or “retest date”</u> of the study drug?	Either a date or some type of indication that the expiration date is being tracked by the sponsor must be present. A telephone log indicating that the sponsor is tracking a study’s drug expiration date is not acceptable. There must be written documentation from the Sponsor that they are monitoring the expiration date. Place retest date onto drug logs as they become available.
7. Does the investigational drug log document the <u>control number</u> of the study drug?	NCQA evaluates control numbers as an identifier that allows the dispensing pharmacist to track the study drug. Lot numbers can also be used as control numbers. Often does not apply to NCI studies.
8. Does the investigational drug log document the date the research protocol was approved (<u>date of IRB approval AND R&D approval</u>)?	The date NCQA uses to evaluate this factor is the VA Research and Development Committee approval date. See Form A. No informed consent may be signed prior to IRB and R&D approvals. NCI sheets do not allow this; need to double-log
9. Does the investigational drug log document <u>the name of the authorized practitioner signing the study drug prescription</u> ?	A variety of documents can be used to meet this factor for NCQA evaluation, including a copy of the physician’s order. The name of the authorized prescriber must be listed on the study’s VA Form 10-9012. Signing practitioners of IP and OP orders are automatically identified in CPRS. Write “CPRS” if electronic order; count as “N/A”. Write “FAX” if HYJ’s form is used; score as Y/N depending on accuracy of the FAXed form.
10. Does the investigational drug log document the <u>name of the patient</u> receiving the prescription?	For NCQA evaluation, a patient name can be a number, initials, and/or a combination of both.

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11. Does the investigational drug log document the <u>serial number of the prescription?</u>	Study drugs that are dispensed in the inpatient setting do not have serial numbers. N/A if processed through CPRS or VISTA (have transaction numbers). Indicate which.
12. Does the investigational drug log document the <u>quantity of study drug dispensed?</u>	
13. Does the investigational drug log document <u>the balance of study drug</u> remaining after the study drug was dispensed (transaction)?	
14. Signed initials of the dispensing pharmacist	
15. Balance adds up	

ADDENDUM FOR DRUG DISPOSAL OR DESTRUCTION

	Guidance / Instructions
16. Date of termination of use of drug:	
17. Reason for termination of use of drug:	Can be for termination of study, expiration of drug, withdrawal of subject, etc.
18. Quantity remaining:	
19. Disposal method:	

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Appendix 6

“Pharmacy Audit Form C: Investigational Drug Service Audit Report”

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AUDITOR: _____ DATE: _____

Research Studies Evaluated for this Audit

Study	Name of Study PI IRB#:	Inpatient / Outpatient	Type (CSP, GCC, Industry, etc.)
A			
B			
C			
D			
E			
F			

REPORT SUMMARY

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General Observations:

PROBLEMS / COMMENTS	CORRECTIVE ACTIONS
Audit given to / discussed with : Pharmacist Name: _____ Date: _____	
Follow-up due date: (or N/A) _____	
Date problems resolved: (or N/A) _____	