

**STANDARD OPERATING PROCEDURE**  
**International Pharmaceutical Excipients Auditing, Inc.**

Title <b>Audit Report Sale</b>		Revision <b>1</b>	SOP Number <b>29</b>
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved <b>March 11,2011</b>	Page Page 1 of 4

**PURPOSE:**

This procedure governs the sale of audit reports to pharmaceutical manufacturers, distributors, or the excipient manufacturer whose site was audited.

**SCOPE:**

This procedure is applicable to both the IPEA Audit Program and the IPEA Excipient GMP Conformance Certification Program.

**RESPONSIBILITIES:**

1. **IPEA Administrator:** The Administrator assures that the excipient manufacturer has approved the sale of the audit report, credit is applied to the audit sponsor, and all records are maintained in accordance with this SOP.
2. **IPEA Executive Management:** The COO or CEO review requests for audit reports no longer considered current and discuss the matter with the Purchaser.

**REFERENCES:**

1. SOP 1, Audit Process Overview
2. SOP 5, Documenting the Audit
3. SOP 9, Certificate of Excipient GMP Conformance
4. SOP 24, Documenting the Certification Audit

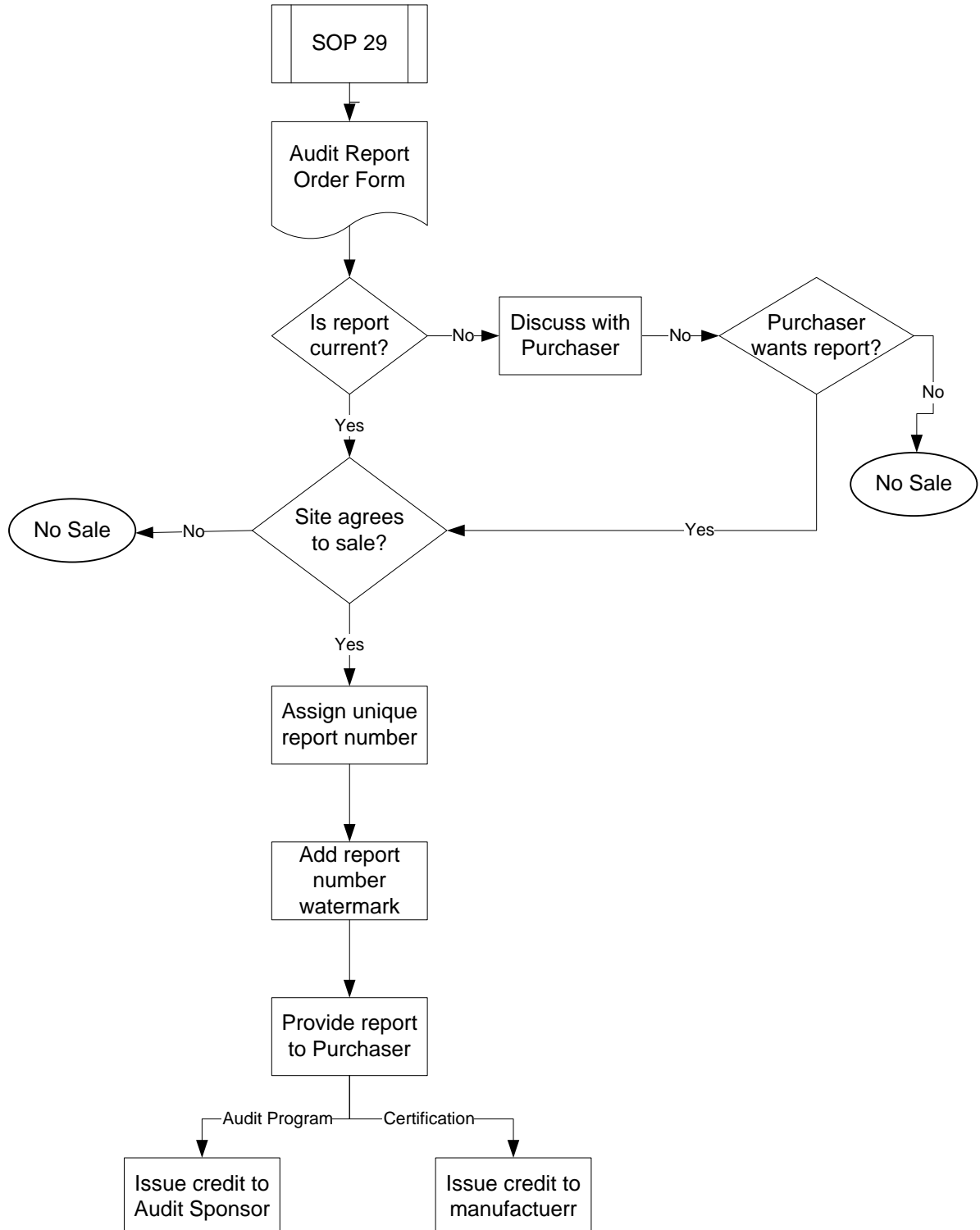
**DEFINITIONS:**

**See Glossary**

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**AUDIT REPORT SALE**



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**PROCEDURE:**

1. IPEA offers for sale audit reports from the Audit and Excipient GMP Conformance Certification Programs as a means to offset some of the cost for the audit sponsor and excipient manufacturer respectively. The reports available for purchase and their purchase price are posted on the IPEA website ([www.ipeainc.com](http://www.ipeainc.com)).
2. The Purchaser completes the Audit Report Order Form located on the IPEA website.
  - a. The Purchaser must request the report by Audit Report Number to assure the correct report is provided.
  - b. Generally only a single copy of the audit report is requested except where the excipient manufacturer or a distributor requests multiple copies of the report.
3. The Administrator assures that the audit report is within its expiry date.
  - a. Where a report has expired, the Purchaser is notified that the audit report is no longer supported by IPEA.
  - b. If the Purchaser still wants to receive a copy of the audit report, the Administrator notifies IPEA Executive Management who discusses the matter of the report not being current with the Purchaser. If the Purchaser confirms they still want to purchase the report, the Site Representative is asked to agree to allow the sale of the report. If the Site Representative rejects the request, the Purchaser is notified by IPEA Executive Management.
4. The Administrator notifies the Site Representative that the Purchaser has requested a copy of their audit report and asks for notification of their concurrence within 7 business days. The Site Representative is informed that a lack of response is taken as agreement for IPEA to sell the report.
  - a. The agreement of the excipient manufacturer to allow the sale of the audit report must be in writing. An electronic communication is suitable and a copy of the communication is maintained.
  - b. If the Site Representative rejects the request for sale of the report, they are asked to provide a reason, e.g. competitor.
5. With agreement from the Site Representative to sell a copy of the audit report, the Administrator assigns a sequential unique number to the audit report that is associated with the Purchaser and inserts that number into the report as a watermark. The report is then provided to the Purchaser as a printed copy unless a request has been made for an electronic copy. Electronic copies are sent in PDF format.

**HISTORY OF REVISIONS**

Revision No.	Effective Date	Description of Changes
0	Mar. 10, 2009	New Procedure

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1	<b>Mar.11, 2011</b>	Added reference to SOP 24, updated diagram and procedure to separate audit program from certification.
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