	POLICIES & PROCEDURES Number: **7311-20-010** Title: **MANAGEMENT OF RECALL NOTICES AND ALERTS**
Authorization [ ] Board of Directors [x] Senior Leadership Team [ ] Vice President	Source: Risk Management Cross Index: Date Reaffirmed: Date Revised: September 2007 Date Effective: June 11, 2002 Scope: SHR and Affiliates

1. POLICY

1.1. Saskatoon Health Region receives recall notices and alerts from multiple external sources such as: manufacturers, distributors, Saskatchewan Health and Health Canada. The Saskatoon Health Region and Affiliates will have a mechanism of coordinating all product and equipment recall notices/ alerts in a timely and efficient manner which will promote safety and reduce risks to individuals and the organization. Recalls and alerts will be assessed on an individual basis, with the responsible department consulting with other stakeholders as required.

1.1.1 Clinical Engineering and Materials Management will coordinate the appropriate follow up for all product and equipment recall notices/ alerts for the Region (including manufacturer and Health Canada recall notices/ alerts).

1.1.2 The Pharmacy Department will coordinate the appropriate follow up for all pharmaceutical recall notices/ alerts for the Region (including manufacturer and Health Canada recall notices/ alerts).

1.1.3 Risk Management will coordinate the appropriate follow up for all Saskatchewan Health Issue Alerts and Health Canada alerts that do not fall under the responsibility of other departments (i.e Pharmacy or Materials Management) for the Region.

1.1.4 Other departments designated as the lead (i.e. Laboratory Medicine, Food and Nutrition, or Public Health) will coordinate the appropriate follow up for product recalls/ alerts for the Region.

2. PURPOSE

2.1 To reduce and eliminate risks related to the use of products or equipment that have been recalled by manufacturers, suppliers or government agencies.

2.2 To identify in a timely and efficient manner the areas affected by the recall notice or alert and ensure appropriate actions taken in a timely manner.

2.3 To document the process and actions taken when recall notice or alerts occur.

2.4 To ensure timely communication with appropriate stakeholders.

3. PROCEDURE

3.1 In the case of product, equipment or pharmaceutical recall notices/ alerts, a designate in the department of Materials Management, Clinical Engineering, Pharmacy or other responsible department (i.e. Public Health) will:

- Identify all Regional facilities, departments and programs affected by the product, equipment or pharmaceutical recall notice/ alert;
- Notify the affected facilities, departments and programs utilizing the attached communication sheet, including what action is required by the manager of the areas affected (Appendix A);
- Coordinate, with the manager of the departments involved, the removal of the product, equipment or pharmaceutical from use (Appendix A);
- Coordinate the shipment of the recalled product, equipment or pharmaceutical to the source;
- When necessary, with the input from affected users, determine replacement or alternate products, equipment or pharmaceuticals;
- Will ensure due diligence by completing all documentation related to the recall process and maintain the file within their department (Appendix A);
- Will promptly report the status of recalls and information regarding any area of procedural non-compliance to Director, Risk Management. This may be done through email notification/ update.

3.2 When product, equipment or pharmaceutical recall notices/ alerts are received by individual user departments, the manager or designate of that unit will:

- Immediately notify the most appropriate department (i.e. Materials Management, Clinical Engineering or Pharmacy);
- Forward all documents received by that department (i.e. Materials Management, Clinical Engineering or Pharmacy);
- The process in 3.1 will then be followed.

3.3 In the case of Saskatchewan Health Issue Alerts, a designate within Risk Management will obtain feedback from key stakeholders on:

- The need for SHR to address the recommendations included in the Issue Alert
- Determine who is in the best position to lead the advancement of each recommendation, if required (Appendix C)
- Notify facilities, departments and programs affected by the Issue Alert using the communication sheets (Appendix B and D)
- Post all Saskatchewan Health Issue Alerts on the infonet
- Ensure those recommendations accepted by the Region are completed in a timely manner
- Will ensure due diligence by completing all documentation related to the recall process and maintain the file within Risk Management

3.4 When replacement or alternate products/ equipment are used, managers or their designate will ensure practitioners in their department are aware of the changes.