Management of Serious Adverse Drug Reactions (SADR) and Medical Device Incidents (MDI) Checklist

REPORTING REQUIREMENT: Federal Legislative Mandatory Reporting Requirements applies to all Acute Care Hospitals/Transitional Health Care Centers including Acute Care Affiliate Health Corporations. Voluntary reporting is encouraged in all health care settings. Serious Adverse Drug Reaction reports are, for the most part, only *suspected associations*. Staff do not have to determine if the health product caused the reaction in order to report. **ADDITIONAL EDUCATION:** A (25 minute) educational video on *"Mandatory Reporting of SADR and MDI for hospitals"* to Health Canada according to the *Protecting Canadians from Unsafe Drugs Act*, also known as Vanessa's Law.	**RESPONSIBILITY**		
	Staff / Prescriber/ Pharmacist	Direct Supervisor/ Manager/Designate	Patient Safety Coordinator
INTAKE			
❑ Complete the applicable Health Canada Serious Adverse Drug Reaction (SADR) Reporting Form for Hospitals &/or the Medical Device Problem Reporting Form for Health Care Professionals immediately, prior to the end of the shift/workday. ***Note:*** *An adverse reaction following a vaccination is a different process refer to: Management of an Adverse Event Following Immunization (AEFI) Checklist.*	⦿		
❑ Submit completed reports immediately to your direct Supervisor/Manager/Designate.	⦿		
❑ The direct Supervisor/Manager/Designate is to review all submissions received to ensure they include the information required by Health Canada. Required information is noted by either a: **single asterisk** (*) = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting) or a **double asterisk** (**) = required (hospital is exempt from mandatory reporting if this information is unavailable)		⦿	
❑ Submit the applicable Health Canada Serious Adverse Drug Reaction Reporting Form for Hospitals &/or the Medical Device Problem Reporting Form for Health Care Professionals to the HealthCanadaReporting@southernhealth.ca within 24 hours of the event. ➢ The Health Canada Mandatory Reporting form for a SADR is to be added/filed in the patient's health record. ➢ The MDI form can be shredded if no patient involvement. If a patient is involved with an MDI then an occurrence report needs to be completed and the MDI form is attached to the occurrence report.		⦿	
❑ Monitors the HealthCanadaReporting@southernhealth.ca email on a daily basis for submissions.			⦿
❑ Follow up immediately, prior to the end of the shift/workday with the submitting facility/program to obtain any required missing information within the facility/program control as needed.			⦿

❑ Log all received reports to the Mandatory Reporting of SADR & MDI tracking log.			⦿
❑ Determine if event meets the threshold/requirement for further internal communication/ notification to applicable sites/programs utilizing the Recalls and Alerts Policy and Procedure ORG.1810.PL.006. Also determines if an occurrence report is required for the event.			⦿
❑ Add facility Identification number to section 10 (*Health Canada Institutional ID*) on the SADR submission &/or to section 13 on the MDI submission. (*ID #'s are located on the tracking log*)			⦿
❑ Add HealthCanadaReporting@southernhealth.ca email address to section 7b on the SADR submission &/or section 8b on the MDI submission.			⦿
DISTRIBUTION			
❑ Fax (1-866-678-6789) the Health Canada Serious Adverse Drug Reaction Reporting Form for Hospitals &/or the Medical Device Problem Reporting Form for Health Care Professionals on behalf of Southern Health-Santé Sud or Affiliate and Community-owned not for profit organizations immediately, prior to the end of the shift/workday.			⦿
❑ Distribute the Recall/Alert Form as deemed applicable and continue to follow the Recalls & Alerts Policy and Procedure ORG.1810.PL.006.			⦿
FOLLOW-UP			
❑ Health Canada will email an acknowledgement number to HealthCanadaReporting@southernhealth.ca for the submission. Upon receipt, add the acknowledgement number to the Mandatory Reporting of SADR & MDI tracking log.			⦿
❑ Create a monthly report for all received and submitted Mandatory Reporting of SADRs and MDIs.			⦿
❑ Distribute the monthly Mandatory Reporting of SADRs and MDIs report via an Admin. Update.			⦿
❑ Annually-(April) Prepare a summary report for all received and submitted SADR and MDI noting themes/trends including meeting the 30-day timeline to Health Canada. The summary report is shared via an Admin.			⦿