CORPORATE POLICY - Serious Incident (SI) Policy

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Revision No:	5
Document ID Number	POLCGR071
Approved By:	Patient Safety Committee
Implementation Date:	October 2016
Date of Next Review:	October 2019

Best of care
Best of people

Document Control / History	
Revision No	**Reason for change**
3.	To incorporate the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation produced by the National Patient Safety Agency 2010
3.1	To incorporate the Human Tissue Authority guidance on reporting and investigating Serious Incidents and Serious Adverse Reactions 2011
4.	Review and update to include Duty of Candour
4.1	Update job titles and SHA & PCT references
5	Serious Incident Management Process – split into policy and see separate SI procedures and reviewed the NHS Serious Incident framework 2015 and related document published in 2016 as well as the Mazar recommendations.

Consultation
Director of Nursing
Chief Executive Officer
Medical Director
Chair of Quality Improvement Committee
Chair of Patient Safety Committee
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Table of Contents

Serious Incident Policy

To be read in conjunction with any policies listed in Trust Associated Documents and Standard Operating Plans (SOP) associated with this policy.

1   Introduction

1.1   Serious Incidents in health care are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.

1.2   The Trust intends to recognise the potential for harm and undertake timely interventions to minimise the impact of the harm or to reduce the possibility of an incident from the same source occurring in the future, where this is possible. Serious incidents are, therefore, subject to thorough investigation in an attempt to identify what factors contributed to the incident. Serious incidents can be isolated incidents or multiple linked, or unlinked, events.

1.3   Responding appropriately when things go wrong in the care and treatment of patients is a key part of the way that the Trust will continually improve the safety of the services that it provides.

1.4   Patient safety is the responsibility of all staff in Medway Foundation Trust. The Executive Team, Directorate leaders and ward/ department managers will model the behaviours expected by a fair and just culture and will set clear expectations around multi-disciplinary involvement with the Serious Incident pathway.

1.5   Responding appropriately to incidents or circumstances that have caused or may cause harm to staff, including contracted staff, or visitors is key to the Trust maintaining the safety and wellbeing of staff and visitors.

1.6   An incident reporting, management and investigation process is a prerequisite to the serious incidents process. This process facilitates the recognition, management and investigation of incidents and enables learning and the minimisation of future harm or loss.

1.7   When an incident has caused significant harm or loss to patients and/or staff, the Trust will respond to and investigate these following this policy which is aligned with the national Serious Incident Framework (March 2015).

1.8   This policy identifies the principles of being open and the legal Duty of Candour (see the Trust's Being Open and Duty of Candour Policy and Procedure). The needs of those affected by the incident will be the primary concern of those I involved in the response to the investigation of an incident.

1.9   When things go wrong, it is the responsibility of the organisation to ensure that there is significant learning from each one to prevent recurrences. The Trust will provide resources to ensure that lessons are learned from each incident. Learning programmes are designed in a variety of formats that are best suited to the information to be shared and the audiences involved.

2   Purpose , Aims and Objectives

2.1   This policy is in place to facilitate staff understanding of what constitutes a serious incident, e.g. Information Governance, Mental Health Act or Pressure Ulcer serious incident.   This policy will assist staff in applying a consistent approach to the management of serious incidents in a timely and open manner so that immediate action can be taken to protect patients and staff, where necessary.

2.2   This document will focus on the identification and management of these incidents, using root cause analysis methodology and facilitating organisational learning from such incidents. This approach aims to reduce the likelihood of the same incidents occurring again or reduce their impact should they occur. This policy will identify the commitment to learning from each incident in a non-judgemental way, so that their recurrence is minimised and to ensure any changes to systems and processes recommended during the root cause analysis are implemented, mechanisms in place to monitor/implement and any necessary changes are made.

2.3   It will set out mechanisms and processes to ensure effective communication with patients, relatives, staff, media and other agencies is maintained at all times and appropriate information is conveyed. This document will set out the reporting arrangements for a Serious Incident to the Trust Board, lead clinical commissioning group (CCG), NHS England, Monitor, the and Care Quality Commission and other external agencies, where necessary, to meet the requirements of external stakeholders.

2.4   The Trust will ensure the process of investigation is open, fair and just, with the primary focus of any Root Cause Analysis based on the investigation of systems and processes, rather than focussing on an individual who may happen to be at the end of a series of faulty processes.

2.5   The identification of lessons to be learned is of the utmost importance to prevent recurrence of similar incidents. The Trust will support learning activities through the use of Grand Rounds, Schwarz rounds, directorate monthly learning activities, quarterly corporate learning events, pop up events and swarm events that are tailored to the learning needs of the audience.

3 Scope

3.1 This policy applies to all permanent, locum, agency, bank and voluntary staff of Medway NHS Foundation Trust.

4 Definitions

4.1 **Incident –** any unexpected or unintended event or circumstance that leads to, or could have led to, harm, loss or damage to people, property or reputation. They may be clinical or non-clinical; e.g. suspected suicide, missing person, fire, theft, violence.

4.2 **Investigation-** A process by which an incident is examined to allow the organisation to consider if actions can be put in place to stop the incident occurring, or reduce the impact, should the incident recur.

4.3 **Patient safety incidents –** any unexpected or unintended event or circumstance that results in, or could result in, harm to a patient.

4.4 **Non-patient safety incidents -** any unexpected or unintended event or circumstance that results in, or could result in, harm to a member of staff (including contractors) or a visitor or loss/damage to the Trust, including financial, asset or reputational loss/damage.

4.5 **Notifiable safety incident** for health service bodies – any *unintended or unexpected incident* that occurred in respect of a patient's care that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in:

- the patient's unexpected death

- **severe harm**:

  a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb, or organ or brain damage, which is directly related to the incident and not to the natural course of the patient's illness or underlying condition.

- **moderate harm**:

  temporary, significant harm which is defined as the lessening of bodily, sensory,

  motor, physiologic or intellectual functions that is directly related to the incident and not to the natural course of the patient's illness or underlying condition and moderate increase in treatment, such as an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another treatment area (such as intensive care, HDU).

- **prolonged psychological harm** for a continuous period of least 28 days

Serious Incident Policy

Identifying an issue as a notifiable safety incident does not automatically imply error, negligence or poor quality care. It indicates that an unexpected and undesirable clinical outcome that resulted from some aspect of the patient's care, rather than their underlying condition and that Medway Foundation Trust has a responsibility to investigate to identify why the incident occurred and to take active steps to correct any

All notifiable safety incidents trigger the statutory Duty of Candour (please refer to the Being Open and Duty of Candour Policy and Procedure).

4.6 **Automatically declared Serious Incidents**
Incidents that are automatically declared as SIs include **(this list is not exhaustive):**

- Never Events (whether or not there was patient harm)

- Falls to fracture

- Maternal death within a year of the birth of an infant

- Hospital-acquired pressure ulcers Grades 3, 4 and unstageable

- Hospital-acquired MRSA bacteremia

- Incidents involving patients being held under the Mental Capacity Act/ DOLS or Mental Health Act

- 12 hour trolley breaches were harm has come to a patient

4.7 **Serious Incident Reports**

- **72 hour report:** a report containing all known facts of the incident that is presented to the CCG within 72 hours of the incident being declared.

- **Level 1 report:** an internal investigation of a less complex Serious Incident using the RCA technique at local level. The completed report is expected to be delivered to the Patient Safety Team within 30-40 working days.

- **Level 2 report**: a comprehensive report on a declared Serious Incident that is presented to the CCG or any other external partner. This report is expected to be completed within 30 days with executive sign off between 30 -40 days. Then delivered to the CCG/ external partner within 60 working days.

- **Level 3** Independent Investigation: this is required where the findings are likely to be challenged or where it will be difficult for the organisation to conduct an objective investigation. Level 3 investigations must be completed within six months of the incident being declared.

4.8   **Apology-** a sincere expression of regret that forms the foundation of the Duty of Candour and is expected to be applied in every Serious Incident (please see p.15 section 8 of this policy and the Trust Duty of Candour Policy and SOP).

4.9   **Datix -** the electronic incident reporting system used by the Trust. Every incident that is considered to be a potential Serious Incident must have a Datix report.

4.10   **Unexpected death-** The death of a patient following a harm-related incident that is not related to the natural course of their disease. Unexpected deaths must be verified and certified by a medical practitioner and reported to the Coroner and would be put on the Trust Datix system.

4.11   **External agencies in which certain types of SI Incidents are report (this list is not exhaustive):**

- NHS England
- Medway CCG/ other relevant CCGs
- Care Quality Commission
- Medicines and Healthcare Regulatory Agency (MHRA)
- HM Coroner
- Police
- Serious Hazards of Transfusion (SHOT)
- Human Tissue Authority
- Adult and Children Safeguarding Boards
- Information Commissioners Office

4.12   **Near miss/prevented incident –** any incident that had the potential to cause harm but was prevented, resulting in no harm. Not every near miss needs to be reported as a Serious Incident but the potential for severity of harm should be a prime consideration.

4.13   **Never Event -** a sub-set of Serious Incidents and are defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented (see Appendix 6 Never Events). These are automatically declared as Serious Incidents. There does not necessarily have to be patient harm in order for an incident to considered a Never Event. These are considered to be automatically declared Serious Incidents.

4.14   **Open, fair and just culture –** Incident reporting, investigation and learning will not be effective in an organisation that does not respond to incidents using the principles and practices of a Just Culture. Traditionally healthcare's culture has held individuals accountable and culpable for all errors or mishaps that befall patients under their care (often referred to as the 'blame & shame' culture). This 'person centered' approach resulted in investigations that failed to identify effective organisational learning. The outcome of these investigations was to unjustly punish

the staff involved but ignore the situation in which the incident occurred. Therefore, incidents were repeated.

4.15   **Root Cause Analysis –** a **systems** approach to investigating an incident to understand how and why it happened and to identify effective actions to prevent the incident from occurring again

4.16   **STEIS (Strategic Executive Information System)** – a Department of Health management information system used to collect information about NHS organisations, including Serious Incidents**.**

4.17   **SWARM:** a multi-disciplinary investigation methodology where involved parties do an intensive review of all available information. To identify contributory factors and to gather evidence to support completion of a draft report.

5   (Duties) Roles and Responsibilities

5.1   **The Trust Board will:-**

- Be made aware of Serious Incidents via relevant reports.

- Receive assurance regarding effective incident management and implementation of incident management policies and procedures from relevant Committees

- Be made aware of any particular concerns and issues in relation to trends or peaks in incidents and of the actions the Trust is taking to address these

5.2   **The Chief Executive**

- The Chief Executive has overall responsibility for the system of internal control and for protecting the health, safety and welfare of all who come into contact with the organisation and is ultimately accountable for the implementation of an organisational wide process associated with the investigation, analysis, learning and subsequent implementation of actions arising from incidents, complaints, contacts and claims. The Chief Executive will ensure that robust processes exist in order to implement the requirements of this policy.

5.3   **Executive Leads**

- The Chief Executive, Medical Director, Director of Nursing and other Executive Directors have a collective responsibility to ensure that this policy and procedure is effectively implemented. This includes ensuring that:

  - the required resources are available to facilitate the implementation of this policy,

  - nominate a Lead Investigator

- the principles of open, fair and just culture are supported and maintained throughout the life of an incident (from reporting through to completion of the report and implementation of the action plan)

- Chair the Harm Free meeting on a rotational basis

- Authorise the declaration of Serious Incidents for reporting to the CCG or other appropriate external bodies

- Sign off all Serious Incident reports for onward transmission to the CCG or other external body as appropriate.

- In the event of a serious non-clinical incident or serious Information Governance Incident, the Director for Corporate Governance, Risk, Compliance and Legal will be the lead executive to oversee the investigation

- Ensure there is a robust process in place and followed for monitoring the implementation of action plans arising from incidents causing significant harm and

- The lead executive retains overall responsibility and accountability for the investigation.

- Upon receipt of the final report, the executive is responsible for signing off the report and for ensuring an associated action plan is developed and implemented based on the recommendations contained within the report and mitigate any risks.

5.4 Patient Safety Team

- The Patient Safety Team will provide advice, support and facilitation throughout the entire Serious Incident process, working primarily with the Directorates to undertake the investigation.

- The Patient Safety Team will provide administration support to liaise with the CCG to report declared Serious Incidents and to provide final copies of reports to the appropriate external bodies

5.5 Lead Investigator will:-

- Conduct a thorough and impartial investigation, using the Root Cause Analysis (RCA) technique. They may call upon any additional resources or personnel e.g. the health and safety advisor, clinical experts, Human Resources, managerial or technical staff may be required to provide specialist advice.

- Hold panel meetings or SWARM events as required and will assist in the taking of statements as necessary.

- Produce a report as directed by the Executive Teams

- Attend the CCG closure meeting

5.6   Directorate Responsibilities

- Each Directorate will ensure that all permanent and temporary staff (including bank, agency and locum staff) receive information during induction on incident reporting and the use of the DATIX web and their responsibilities under the legal Duty of Candour process.

- Each Directorate will ensure timely investigation of incidents within the required time frame.

- Directorate leads will support the investigation process by ensuring that there is sufficient time and resources to conduct the investigation. Staff are required to attend both MDT meetings and any organised SWARM events.

- Action plans arising from investigations are the responsibility of the Directorate Management and each department within each directorate is responsible for implementing changes where appropriate. The Directorate management team are responsible for ensuring that all actions are implemented and assurance given to the SI Executive Group.

- Directorate Leads are responsible for ensuring that there is a clear plan for sharing lessons learned from each Serious Incident, in collaboration with the Patient Safety Team.

5.7   All staff

- All staff have a responsibility to read and understand this policy.

- All staff have a duty to report any incident, including serious incidents and to take immediate steps to protect individuals, information or the environment.

- All members of Medway NHS Foundation Trust – whether permanent , locum, agency or contractors- whatever occupation or seniority- are required to co-operate with all investigations as requested.

- Staff are entitled to be accompanied by a member of a Trade Union or other staff side representative when giving statements or when being interviewed in the course of an incident investigation.

- Arrangements for staff support following a Serious Incident will be provided by the Directorate Management Team who may also make a referral to the Occupational Health Team as required.

6   Committee and Oversight Responsibilities

6.1   **Directorate Incident Review/ Governance Committees** meet weekly as a multi-disciplinary team to discuss all incidents that have been reported in the Directorate in the past week.

6.2 **Harm Free Group**- the Harm Free Group meets weekly to review incidents that **have** been reviewed at Directorate level as being moderate or severe harm incidents or unexpected deaths. This group is chaired by the Chief Quality Officer, the Director of Nursing or Medical Director on a rotational basis. The Chair is responsible for declaring Serious Incidents that will uploaded to STEIS to notify the CCG.

6.3 **Executive Sign Off-** two Executive Leads must sign off a declaration of a Serious Incident for reporting to the CCG or other body.

7   Incident Definitions

7.1 A Serious incident (SI) is an accident or incident when a patient, member of staff or a member of the public suffers serious injury, unexpected or avoidable serious harm or death in hospital or other premises where NHS care is provided. Serious Incidents include acts or omissions in care that result in unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm which is either permanent (severe) or temporary (moderate) - including those incidents where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.

The declaration of a Serious Incident should err on the side of caution. The Trust should not wait for the outcome of a full investigation before reporting to the CCG. If it subsequently emerges that an incident does not meet the criteria for a Serious Incident, the commissioner should be approached to downgrade the incident and remove it from STEIS.

7.2 Serious incidents may be identified through various routes, including, but not limited to:

- Incidents identified during the provision of healthcare
- complaints
- claims
- whistle blowing
- Serious Case Reviews
- safeguarding children and adults reviews/ enquiries
- prevention of Future Deaths Reports issued by the Coroner

7.3 This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- a Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.

- major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

- an incident (or series of incidents) that prevents, or threatens to prevent, an organisation"s ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

  o failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues

  o property damage;

  o security breach / concern;

  o incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;

  o inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS); The Department of Health have updated their guidance on investigations and the application of Article 2 of the European Convention on Human Rights. This should be read in conjunction with the NHS England Serious Incident Framework;

  o the placement of children or young people, under the age of 18 years, on an adult psychiatric ward;

  o unauthorised absences of a person detained, or liable to be detained, under the Mental Health Act 1983 in relation to low, medium or high security levels (applicable to Bowman Ward).

  o significant healthcare associated infections i.e. an outbreak of infection that closes a ward/unit, failure in decontamination or infected healthcare worker.

  o maternity, infant and child incidents as described in the NPSA National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.

  o death of a patient, or a person using the service, who is detained, or liable to be detained, under the Mental Health Act 1983.

  o Ionising Radiation incidents

  o systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or

  o activation of Major Incident Plan (by provider, commissioner or relevant agency)

7.4 If staff have concerns about unsafe practice, poor staffing, issues of professional misconduct or institutional neglect, they can report these in the first instance through a line manager, by following the Raising Concerns at Work (whistleblowing policy) or by seeking advice from the Trust's Safeguarding Team.

7.5 Incidents are graded according to the level of harm or whether they have been identified as a Never Event. Incidents that may be classed as Serious Incidents are those where there has been moderate or severe harm, unexpected death or a Never Event. Definitions of each of these categories are found below and this list is not exhaustive.

8   Duty of Candour

8.1 The Trust recognises the importance of full, open and honest communication in feeding back to patients or their nominated representative. There is a duty to give a genuine apology and an explanation of the facts as they are known at the time of the first discussion.

8.2 The most responsible senior clinician will lead this discussion and invite the patient or their representative to identify any questions that they may have to be answered by the investigation committee. They will be informed of investigation timelines and will be invited to meet to discuss the outcome of the investigations.

8.3 The Duty of Candour Policy and Procedure provide full details.

9   Learning Lessons

9.1 Serious incident investigation reports should identify specific recommendations for improvement. These recommendations are supported by actions for completion by an identified lead within a defined timescale. The Directorate Management Team is responsible for following up and reporting on compliance with agreed actions and confirming that embedded learning has been achieved.

9.2 The Trust is committed to ensuring robust investigations are conducted which result in the organisation learning from SIs to minimise the risk of the incident occurring in the future, or to reduce the potential harm, and, as such, expects any actions to result in "embedded learning".

9.3 Embedded learning is defined as a change of behaviour at individual, team or organisational level. If appropriate, the serious incident investigation executive summary, or report, can be shared. The executive summary includes a précis of the incident and investigation and is fully anonymised to preserve confidentiality of the people involved. This will enable the executive summary to be widely shared. Learning can be shared from individual investigations or as an aggregate of similarly themed incidents. Learning programmes can take a variety of forms and the information can be tailored to suit the audience.

Serious Incident Policy

10   Monitoring and Review

What will be monitored	How/Method/ Frequency	Lead	Reporting to	Deficiencies/ gaps Recommendations and actions
Policy review	First review in one year and then every three years	Head of Patient Safety	Patient Safety Group, Quality Improvement Group	This policy will be reviewed in conjunction with any legislation changes and Trust objectives A revised Policy will be published via the Trust Intranet System for global access.
Numbers of Serious Incidents by Directorate by category	SIs will be reported monthly	Head of Patient Safety	Trust Board (monthly), Patient Safety Group and Quality Assurance Group (monthly) and the Quality Improvement Group (bimonthly)	Any gaps/deficiencies will be reviewed and necessary action taken to resolve these
Trends and Themes reviews	Quarterly thematic reports quarterly	Head of Patient Safety	Trust Board, Patient Safety Group and Quality Assurance Group (monthly) and the Quality Improvement Group	Any gaps/deficiencies will be reviewed and necessary action taken to resolve these
Audit	Yearly	Head of Patient Safety	Patient Safety Group	Any gaps/deficiencies will be reviewed and necessary action taken to resolve these

11   Training and Implementation

11.1   The Trust shall provide training and support to managers and their delegated representatives to enable them to fulfil their responsibilities in the local investigation of incidents.

11.2   The Trust will train Lead Investigators in Root Cause Analysis investigation techniques. Those who have been trained will undertake the investigation of Serious Incidents as directed by the Director of Nursing or Medical Director/Chief Quality Officer.

11.3   Over time, a pool of individuals nominated to lead on investigations will be developed. The scope of this training will be :

- Incident reporting procedure and reasons for reporting and investigation

- Principles of investigation and Root Cause Analysis. (National Patient Safety Agency (NPSA) Model and internal model)

- Record keeping

- Identification and implementation or remedial action to prevent recurrence.

- Risk evaluation/Risk grading

- The root cause analysis toolkit is available for all staff from http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/rootcauseanalysis/rca-investigation-report-tools/

12   References

Document	Ref No
References	
NHS England Serious Incidents Framework (March 2015)_ found via website on 08 August 2016: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/03/serious-incdnt-framwrk-faqs-mar16.pdf	Guidance
NHS England Serious Incidents Framework (2016) https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf	Guidance
Cornwall Partnership NHS Foundation Trust Serious Incident Policy 2015	Policy
[3]Marks David, Patient Safety & the 'Just Culture': A Primer for Health Care Executives, 2001	
Reason James Managing the Risks of Organisational	

Accidents in 1997 (and subsequent work)	
Trust Associated Documents	
Risk Management Strategy	POLCS017
Slips, Trips and Falls	POLCGR057
Duty of Candour	POLCGR064
Medicine Management Policy	POLCPCM033
Safeguarding Vulnerable Adults	GUC PCM 002
Child Protection Policy and Procedure	POLCPCM027
Infection Control Policies	
Business Continuity Policy	OTCOM006
Tissue Viability Policy	POLCNM001
Supporting Staff Involved in Complaints, Claims and Incident Policy	POLCGR102
Resuscitation Policy	POLCPCM032
Serious Incident Pathway	OTCGR145
Serious Incident SI - Procedure	SOP0039
Serious Incident SI - Death Process	SOP0080
Serious Incident SI - Reporting to Clinical Commissioning Group - CCG	SOP0075
Serious Incident SI - Definitions for Serious Incidents Never Events	OTCGR146
TEMLATE - Serious Incident SI - Level 1 Investigation Report	
TEMLATE - Serious Incident SI - Level 1 Investigation Report	
TEMPLATE - Serious Incident SI - 72 hour report	
TEMPLATE - Serious Incident SI - CCG Downgrade Request Form	
SI Resource Pack	

END OF DOCUMENT