<table>
<thead>
<tr>
<th>NAME OF DOCUMENT</th>
<th>Safe Handling and Management of Monoclonal Antibodies</th>
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<tbody>
<tr>
<td>TYPE OF DOCUMENT</td>
<td>Procedure</td>
</tr>
<tr>
<td>DOCUMENT NUMBER</td>
<td>SESLHDPR/368</td>
</tr>
<tr>
<td>DATE OF PUBLICATION</td>
<td>April 2015</td>
</tr>
<tr>
<td>RISK RATING</td>
<td>Extreme</td>
</tr>
<tr>
<td>LEVEL OF EVIDENCE</td>
<td>NSQHS Standard 4 and 15</td>
</tr>
<tr>
<td>REVIEW DATE</td>
<td>April 2016</td>
</tr>
<tr>
<td>FORMER REFERENCE(S)</td>
<td>Nil</td>
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</table>
| EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR | Sharon Litchfield  
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| KEY TERMS        | Monoclonal Antibodies, MABs, Cytotoxic, Occupational Exposure |
| SUMMARY          | This procedure has been developed to ensure processes are in place to manage the potential risk to workers health when using Monoclonal Antibodies in the workplace. |
1. POLICY STATEMENT

The use of Monoclonal antibodies (MABs) within cancer and other services has been expanding within our organisation and as they are not like traditional anticancer agents, they often do not fulfil the criteria for classification as cytotoxic or hazardous substances.

As there is currently limited research on the long term effects of MABs, SESLHD has decided to adopt the risk management principles outlined in Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel

This procedure is intended to be used by workers who are involved in the handling of MABs in cancer treatment or other services and is applicable to but limited to medical, pharmacy and nursing staff.

2. DEFINITIONS

Monoclonal antibodies (MABs): A type of protein made in the laboratory that can bind to substances in the body, including cancer cells. A monoclonal antibody is made so that it binds to only one substance. Monoclonal antibodies are being used to treat some types of cancer and can be used alone or to carry drugs, toxins, or radioactive substances directly to cancer cells.

NHMRC : National Health and Medical Research Council

Personal Protective Equipment (PPE): Safety equipment provided to reduce the risk of exposure to specific MABs

3. RESPONSIBILITIES

3.1 Workers will:
- Check Monoclonal Risk Rating and Safety Data Sheets or instructions provided by the drug manufacturer to identify the risk level and PPE prior to handling or using the MAB
- Report spills or any exposure to your manager and follow safety advice outlined by the manufacturer
- Participate in Occupational Exposures program if handling High Risk MABs

3.2 Line Managers will:
- Ensure workers are provided with appropriate PPE
- Where workers are required to handle MABs identified as high risk, arrange baseline assessments for health monitoring as per Occupational Exposures Procedure
- Report any new MABs that are not in Monoclonal Risk Rating to their Senior Manager

3.3 Seniors Managers will:
- Support the program in place for Health monitoring and safe handling of MABs
- Report any new MABs that are not in Monoclonal Risk Rating to Drug & QUM Committee
3.4 **Medical staff will:**
- Check [Monoclonal Risk Rating](#) and Safety Data Sheets or instructions provided by the drug manufacturer to identify the risk level and PPE prior to handling or using the MAB
- Report spills or any exposure to your manager and follow safety advice outlined by the manufacturer
- Participate in Occupational Exposures program if handling High Risk MABs

3.5 **Drug & QUM Committee will:**
- Review newly identified MABs to ensure they are risk rated and the appropriate controls such as PPE are documented

4. **PROCEDURE**
The general principles to implementing this procedure as outlined below in Flowchart 1

**Flowchart 1**

Identify risk rating for specific MAB – [Monoclonal Risk Rating](#)

Follow Personal Protective Equipment (PPE) instructions based on risk rating in [Monoclonal Risk Rating](#)

- High Risk MABs
  - Prepare MAB as per local arrangements for cytotoxic/hazardous drugs
  - Follow Occupational Exposures Procedure
  - Report any spills or accidents with MABs to line manager

- Moderate Risk MABs
  - Prepare in safe environment (i.e. pharmacy, ward, clean-room or clinic).
4.1 Risk Identification and Controls
Where a MAB is being used the worker is to check Monoclonal Risk Rating to identify the risk rating of the specific MAB along with the Handling Precautions. The Safety Data Sheets or instructions provided by the drug manufacturer are to also be check for additional information and the highest level of controls either manufacturer or SESLHD guide are to be implemented.

4.2 Unlisted MABs
If the MAB is not listed in Monoclonal Risk Rating it is to referred to the Manager and then on to the Drug Drug & QUM Committee for review. In this case the drug manufacturer safety instructions and Safety Data Sheets will be the minimum requirement until otherwise advised.

4.3 Use of Personal Protective Equipment (PPE)
Current research indicates the most likely absorption risks are through dermal absorption such as damaged skin (cuts, open wounds), Inhalation or oral absorption. The likelihood of producing an aerosol with the required physical characteristics in the healthcare setting is limited.

For this reason the correct fitting of Personal Protective Equipment (PPE), along with using the appropriate PPE is imperative in reducing the risk of exposure to workers.

The recommended PPE as outlined in Monoclonal Risk Rating must be used by workers and if it not available the Manager is to be notified so it can be arranged before handling or using the MAB.

4.4 Preparation of MABs
Moderate Risk MABs require aseptic transfer techniques and the recommended PPE to be used.

High Risk MABs where possible are to be prepared by a centralised service in the same safety cabinets as cytotoxic agents, appropriate cleaning and decontamination should occur between preparations of cytotoxic agents and these MABs. If this is not possible, a closed system drug transfer device should be used for the preparation of all cytotoxic items to minimise surface contamination of the end product.

4.5 Disposal
Disposal of waste products associated with MABs (including patient waste) should be in accordance with the disposal of clinical waste. This applies to waste production during preparation and administration, as well as patient waste.

4.6 Spills Management
Should a spill relating to the MAB occur the PPE listed in Monoclonal Risk Rating must be used. For a medium risk MAB waste should be disposed of in accordance with clinical waste guidelines.
In the case of high risk MABs, spills are to be managed in accordance with the Safety Data Sheet provided by the manufacturer. If the MAB contains a cytotoxic agent then a cytotoxic spill kit may be required depending on the amount of product spilt. This spill must be reported to Sector Work Health and Safety Unit who will assist with further reporting if required.

4.7 Staff Training
The Manager is to ensure training is provided to workers in their department prior to them conducting work with MABs and as a minimum includes:
- Aware of the requirements set out in this procedure
- Training in the specific Safe Work Procedures for medium and high risk MABs
- Competency in aseptic transfer techniques
- Complex dosing calculations or complex reconstitution techniques
- Safe handling of cytotoxic drugs for workers who handle cytotoxic MABs

Through Cancer Institute NSW, there is an Antineoplastic Drug Administration Course (ADAC) which may be a useful resource for workers. Link - evIQ Education (required free registration to access).

4.8 Health Monitoring
Where workers are handling and dispensing high risk MABs, the Manager will implement health monitoring as outlined in the Health Monitoring - Occupational Health Exposures other than Infectious Diseases.

5. DOCUMENTATION
Workers are required to document the use of MABs as part of their standard medication documentation processes.

6. AUDIT
Clinical incidents relating to MABs will be audited based on reports within the Incident Information Management System.

7. REFERENCES

7.1 External
- Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel
- Health Monitoring for Exposure to Hazardous Chemicals: Guide for Workers
- COSA and CPG Position Statement - Safe handling of monoclonal antibodies in healthcare settings
7.2 Internal

- Health Monitoring - Occupational Health Exposures other than Infectious Diseases.
- SESLHDPR353 Clinical Waste Management In Healthcare Facilities
- Resource Document Safe Handling and Waste Management of Hazardous Drugs

8. REVISION AND APPROVAL HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision No.</th>
<th>Author and Approval</th>
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<tbody>
<tr>
<td>September 2014</td>
<td>1</td>
<td>New procedure - Author - Peter Kuszelyk. Endorsed by Executive Sponsor, Sharon Litchfield</td>
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<tr>
<td>February 2015</td>
<td>1</td>
<td>Endorsed by D&amp;QUMC on 12 February 2015</td>
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<tr>
<td>March 2015</td>
<td>1</td>
<td>Endorsed by CQC on 11 March 2015</td>
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<tr>
<td>June 2015</td>
<td>2</td>
<td>Hyperlink added to SharePoint page - <a href="http://sesinet/sites/HSW/Monoclonal/Pages/default.aspx">http://sesinet/sites/HSW/Monoclonal/Pages/default.aspx</a> and Appendix 1 removed</td>
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