THIS INSPECTION IS BASED ON WV PHARMACY LEGISLATIVE RULES & LAW
AND THE MOST CURRENT VERSION OF USP 797

<table>
<thead>
<tr>
<th>POLICIES &amp; PROCEDURES &amp; DOCUMENTATION MUST ADDRESS AT LEAST THE FOLLOWING:</th>
<th>Y</th>
<th>N</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DOCUMENTATION OF TRAINING OF PERSONNEL IN BASIC FUNDAMENTALS OF STERILE COMPOUNDING PROCEDURES.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>DOCUMENTATION OF TRAINING &amp; OBSERVATION OF PROPER HAND HYGEINE &amp; GARBING TECHNIQUES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>DOCUMENTATION OF TRAINING &amp; OBSERVATION OF ASEPTIC TECHNIQUE &amp; MANIPULATION OF EQUIPMENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>DOCUMENTATION OF MEDIA FILL TESTING ANNUALLY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>DOCUMENTATION OF GLOVED FINGER TEST, INITIAL &amp; ANNUAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>WRITTEN PROCEDURES FOR CLEANING &amp; DISINFECTION ON DAILY BASIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>CURRENT AND PRIOR CERTIFICATION RECORDS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>WRITTEN PROCEDURES FOR CLEANING &amp; DISINFECTION ON MONTHLY BASIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>WRITTEN PROCEDURES OF SPECIFIC CLEANING AGENTS TO BE USED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>WRITTEN PROCEDURES FOR USE OF STERILE IPA ALCOHOL FOR DISINFECTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>CLEANING PROCEDURES INCLUDE EQUIPMENT TO BE USED &amp; THEIR STORAGE LOCATIONS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>PEG EQUIPMENT IS CLEANED BEFORE EACH SHIFT &amp; ROUTINELY DURING THE COMPOUNDING ACTIVITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>CUSTODIAL STAFF IS TRAINED IN CLEANING PROCEDURES &amp; PROPER DISPOSAL OF WASTE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>WRITTEN PROCEDURES FOR CLEAN UP OF BREAKS &amp; SPILLS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>RECIPIES &amp; FORMULAS ARE DOCUMENTED FOR COMMONLY PREPARED STERILE PRODUCTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>WORKSHEETS ARE MAINTAINED FOR EACH CSP PREPARED &amp; ARE SIGNED BY COMPOUNDING PERSONS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>ALL TECHNICIAN CALCULATIONS ARE CHECKED BY A PHARMACIST PRIOR TO MIXING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>LABELING OF COMPOUNDED STERILE PRODUCTS IS DONE ACCORDING TO RULE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>ALL PACKAGED &amp; LABELED CSP'S ARE VISUALLY INSPECTED BY A PHARMACIST &amp; DOCUMENTED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>DOCUMENTATION ON PROPER STORAGE &amp; HANDLING OF RAW MATERIALS &amp; COMPLETED CSP's</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>THE STORAGE REQUIREMENTS &amp; DELIVERY OF COMPLETED COMPOUNDED STERILE PRODUCTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>OPENED OR PARTIALLY USED PACKAGES FOR LATER USE ARE PROPERLY LABELED &amp; STORED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>THE CRITERIA FOR DETERMINING BEYOND USE DATING (BUD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>PROPER PROCEDURES FOR REPORTING &amp; DOCUMENTING ADVERSE REACTIONS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>* THE ANTEROOM MAINTAINS AN ISO 8 ENVIRONMENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>* THE ANTE ROOM IS SEPERATED FOR THE BUFFER(CLEAN) ROOM BY A LINE OF DEMARCATION OR DOOR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>*THE BUFFER(CLEAN) ROOM HAS HANDS FREE ACCESS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>*THERE ARE NO SINKS OR DRAINS IN THE BUFFER(CLEAN) ROOM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>29</td>
<td>* THE BUFFER (CLEAN) ROOM IS MAINTAINED AT ISO 7 ENVIRONMENT</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>30</td>
<td>* BUFFER ROOM FOR COMPOUNDING MAINTAINS POSITIVE AIR PRESSURE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>* AIR SAMPLING &amp; CERTIFICATION OF ROOM ISO STANDARDS IS DONE AT LEAST SEMI-ANNUALLY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>* ALL SURFACES OF CLEAN ROOM ARE SMOOTH, SEALED &amp; FLOOR JUNCTURES ARE COVED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>* PLACEMENT OF PRIMARY ENGINEERING CONTROLS CONFORM TO USP 797 GUIDELINES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>PLACEMENT OF PRIMARY ENGINEERING CONTROLS PERMIT CLEANING OF ALL SURFACES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>SURFACE SAMPLING OF WORK AREAS WITH GROWTH MEDIUM IS DONE &amp; CULTURED &amp; RESULTS LOGGED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>REQUIREMENTS OF AIR CHANGES PER HOUR (ACPH) IN ROOMS AND PEC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>THE PHARMACY MAINTAINS A WRITTEN QUALITY ASSURANCE PROGRAM WITH ANNUAL UPDATES</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If the facility meets "Low-Level CSP with 12 hours or less BUD" guidelines, it does not need to meet these requirements.

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>A COPY OF USP CHAPTER &lt;800&gt; IS AVAILABLE IN THE PHARMACY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>ENTITIES THAT HANDLE HDS MUST INCORPORATE CHAPTER&lt;800&gt; STANDARDS INTO THEIR OCCUPATIONAL SAFETY PLAN.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>AN UP TO DATE COPY OF THE NIOSH LIST OF ANTINEOPLASTICS AND OTHER HDS USED IN HEALTHCARE IS MAINTAINED AND REVIEWED ANNUALLY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>PERSONNEL MUST THOROUGHLY UNDERSTAND THEIR RESPONSIBILITIES OF FUNDAMENTAL PRACTICES AND PRECAUTIONS OF HANDLING HDS AND AN ONGOING EVALUATION SYSTEM IN PLACE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>PROPER SIGNAGE FOR THE HAZARD IS DISPLAYED AT THE HD HANDLING AREAS (RECEIVING AN UNPACKING, STORAGE AND COMPOUNDING OF HDS) AND ONLY ACCESSIBLE TO AUTHORIZED PERSONNEL.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>HDS ARE STORED IN A SEPARATE AREA ON PROPER SHELVING (NOT ON THE FLOOR) IN A NEGATIVE PRESSURE ROOM WITH AT LEAST 12 ACPH (NON-STERILE) OR 30 ACPH (STERILE).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>STERILE AND NON-STERILE HDS MUST BE COMPOUNDED WITHIN A C-PEC LOCATED IN A C-SEC EXTERNALLY VENTED THRU A HEPA FILTER AND HAVE A NEGATIVE PRESSURE BETWEEN 0.01 AND 0.03 INCHES OF WATER COLUMN RELATIVE TO ALL ADJACENT AREAS WITH APPROPRIATE ACHP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>IN ADDITION TO CHAPTER &lt;800&gt; STERILE COMPOUNDING MUST FOLLOW STANDARDS IN &lt;797&gt; THAT THE C-PEC PROVIDES ISO CLASS 5 AIR LOCATED IN A C-SEC OF ISO CLASS 7 AND AT LEAST 30 ACPH AND THE ANTEROOM BE OF ISO CLASS 7.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>SINK IS IN ANTE-ROOM AT LEAST 1 METER FROM ENTRANCE TO HD BUFFER ROOM.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>PROPER BUDS ASSIGNED BASED ON AREA IN WHICH COMPOUNDED AND RISK LEVEL.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>BSC &amp; CACI CABINETS EXHAUST THROUGH A HEPA FILTER &amp; THEN VENT OUTSIDE, SIX FEET ABOVE HIGHEST ROOF POINT.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49</td>
<td>GLOVES FOR STERILE HD COMPOUNDING ARE STERILE CHEMOTHERAPY POWDER FREE GLOVES.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>GOWNS ARE DISPOSABLE AND NON-PERMEABLE THAT CLOSE IN THE BACK, LONG SLEEVES AND ELASTIC CUFF.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51</td>
<td>TWO PAIR OF SHOE COVERS ARE DONNED BEFORE ENTERING THE C-SEC AND DOFFED WHEN EXITING THE C-SEC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>ALL PPE WORN DURING HD COMPOUNDING IS CONSIDERED CONTAMINATED AND DISPOSED OF PROPERLY ACCORDING TO LOCAL, STATE AND FEDERAL REGULATIONS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53</td>
<td>IS ENVIRONMENTAL WIPE SAMPLING PERFORMED? (NOT REQUIRED AT PRESENT - BEST PRACTICE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54</td>
<td>DOCUMENTATION OF PERSONNEL OF REPRODUCTIVE CAPABILITIES UNDERSTANDING THE RISKS OF HANDLING HDS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55</td>
<td>SOPS TO ENSURE PROPER TRAINING OF PERSONNEL REGARDING PROPER RECEIVING, LABELING, TRANSPORT, STORAGE AND DISPOSAL OF HDS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>56</td>
<td>TRAINING AND COMPETENCY ASSESSMENT IS DONE AT LEAST ANNUALLY AND DOCUMENTED (INCLUDING CUSTODIAL PERSONNEL).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>57</td>
<td>A SPILL KIT IS ACCESSIBLE IN THE RECEIVING AREA AND ALL OTHER AREAS HAVING HDS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>58</td>
<td>SPECIFIC SOP IN PLACE TO PREVENT SPILLS AND TO MANAGE THE CLEAN UP OF HD SPILLS AND DOCUMENTATION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>59</td>
<td>SOPS ARE REVIEWED ANNUALLY AND DOCUMENTED AS SUCH.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>IS THERE AN INSTITUTED MEDICAL SURVEILLANCE PROGRAM? (NOT REQUIRED / BEST PRACTICE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>61</td>
<td>POLICY AND PROCEDURES IN PLACE TO ENSURE WORKER SAFETY DURING ALL ASPECTS OF HANDLING HDS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Inspector Comments:

<table>
<thead>
<tr>
<th>Pharmacist-in-Charge</th>
<th>Date</th>
<th>Inspector</th>
<th>Date</th>
</tr>
</thead>
</table>