

# Standard Operating Procedure

## Title: Protecting the Reliability of Electronic GMP Records

Conversely mark 'N' (No) where the attribute is not protected.

Some control measures can support more than one reliability-attribute, in such cases mark all columns affected. Some control measures cannot be implemented for the type of record that is generated (e.g. electronic backups of paper records) – in this case mark the cell as 'N/R' (Not Required).

To assist this assessment, certain cells on Form 710 have been shaded where it is considered unlikely that a control measure will provide any benefit. Shaded cells may be left blank where the answer would otherwise be 'No' or 'N/R'.

### 2.5.3. Compare against Minimum Reference Standard

Each control measure on Form 710 has been assigned a Minimum Reference Standard, suggesting the lowest level of Impact at which it might be considered appropriate. This determination was based on the nature of the measure (how complex, costly and common it is to implement) and any specific GMP requirements. Appendix 1 includes references to cGMP and PIC/S documents suggesting each measure. The most basic and fundamental measures have been labelled "*No-Impact*", while the more rigorous as "*Direct*" Impact.

Compare the Minimum Reference Standard label for each control measure with the GMP Impact rating for the record, determined in Step 2.2 (above). Control measures that are labelled "*Direct*", "*Indirect*" or "*No-Impact*" should be considered for records with Direct Impact. Records with No-Impact may be adequately protected by "*No-Impact*" measures alone.

### 2.5.4. Comment on any Variations

Assess and document on Form 710 the outcome of the comparison (step 2.4.3) for each control measure. Table 2 illustrates some suggested comments for various conditions of implementation:

<b>Outcome of Control Measure Assessment</b>	<b>Suggested Assessment</b>
The control measure has been implemented effectively	"Adequate"
The control measure has been implemented, but its effectiveness is restricted by certain factors or circumstances	"Limited by ..."
The control measure has not been implemented and the Impact rating of the record is less than the Reference Standard for the measure.	"Appropriate omission"
The control measure has not been implemented and the Impact rating of the record is not less than the Reference Standard for the measure.	"Potential Vulnerability" OR "Not Required because .. ( <i>usage mode, presence of other controls, other factors</i> )"

The comment field may also be used to document any additional information relevant to the Control Measure (e.g. names of SOPs, implemented features).

Note that control measures corresponding to Impact ratings greater than that of the record might be implemented for reasons other than GMP compliance (e.g. to comply with IT security standards or to protect other business risks). The presence of these measures should be documented.

### 2.6. Assess the Total Control Strategy

After assessing all of the control measures separately, the adequacy of the total control strategy should be assessed. The following factors are relevant to this consideration:

- Are all reliability-attributes covered by the strategy?