

**Subject:** FR Notice Comments - 72FR52130: LLNA Performance Standards

**Date:** Monday, September 24, 2007 11:39 AM

Below is the result of your feedback form. It was submitted by  
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Comment\_date: 24 September 2007

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Comments: This is welcome development, the general approach seems sound, and I have only a few constructive comments at this stage.

1. The document does not set out the need for or divers of a need to develop and validate alternative indices of lymphocyte proliferation.

2. At 2.3.2.2, after line 419, details of all audits and copies of all audit reports should be included.

3. Appendix A, animal selection and preparation, animal species selection: lines 633/634: ths gender and strain are separate consideration and should be listed as separate bullet points.

4. Annex A, animal preparation, line 647 - the acclimitization period whould be AT LEAST 5 days. Also it is not clear if ear-punching or -notching or ear-clips are acceptable means of marking/identifying animals.

5. Annex A, selection of doses, line 699. Whilst it is reasonably clear to those familair with the key reference documents what is in tended, strictly speaking in plain English consecutive doses wold by 100%, 99%, 98% etc.

