

IMAGE-ASSISTED CYTOLOGY WORKLOAD SURVEY CHANGE REQUEST:

Nonmaterial/ non-substantive changes are requested for Image-Assisted Cytology Workload Assessment and Measure ICR (OMB # 0920-1000), which includes Attachment C: Image-Assisted Cytology Workload Assessment Survey-Laboratory and Attachment D: Image-Assisted Cytology Workload Assessment Survey –Cytotechnologist. Justification for the non-substantive change requests are described below and detailed in the chart below. There are no requested changes in the scope of the study, the methodology, statistical methods, or significant changes to the respondents, information collection instruments, or burden.

The primary change request is to reformat the survey instrument forms to deliver the survey via Survey Monkey as a single online survey, rather than two paper surveys to be delivered by mail. There are corresponding changes in the format of the survey due to change in the delivery mode. These changes include: adding demographic questions, reformatting questions, reordering questions and changing all correspondence documents (cover letter, reminders, thank you) to an online email format. The additional demographic questions will increase the robustness of the collected data as it will allow for stratification in the analysis by characteristics of the labs; the online skip patterns and question logic allows for only applicable questions to be asked of respondents, and assure that respondent burden will not be increased. Additional changes are requested to include a Don't Know (DK) option to all relevant response categories. Lastly, a change is requested to include incentives, including cytology educational materials, in the form of a random drawing of completed surveys.

The reason for the request to change to an online delivery format is to increase the efficiency of completing the survey. The online format also allows for skip logic patterns to be included in the survey which will assure that respondents are not asked questions that are not applicable based on their previous responses; this will be a benefit to respondents in reducing response errors. The random drawing of prizes for completing the survey includes a variety of educational materials. These incentives are included to encourage participation and increase the response rate because respondents are asked to complete the survey during working hours.

The currently approved data collection instrument (Attachment C and Attachment D) are attached along with the online data collection screen shots from Survey Monkey (pdf file).

Form	Current Question/Item	Requested Change
<p>Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory</p> <p><i>and</i></p> <p>Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist</p>		<p>REFORMATTING FORM</p> <p>-Instead of 2 paper surveys, changed to 1 online form with skip logic included</p> <p>-added introduction to online survey,</p> <p>-added thank you screen after survey is completed</p>
<p>Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory</p> <p><i>and</i></p> <p>Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist</p>		<p>ADDING NEW QUESTIONS:</p> <p><u>Demographic questions:</u></p> <p>Q1: Where is your laboratory located?</p> <p>Q 3: How many automated microscopes of the following image-assisted screening devices are used in your laboratory, if any?</p> <p>Q 4: Please enter the 10-digit CLIA number for your laboratory as indicated on the CLIA certificate.</p> <p>Q5: What is the name of your laboratory?</p> <p>Q 7: Are you male or female?</p> <p>Q 8: Which category lists your age?</p> <p>Q9: What is your position?</p> <p><u>Additional questions:</u></p> <p>Q 34: How are screening activities defined by your laboratory? (Please select all activities that are considered screening activities.)</p> <p>Q 46: Would you be willing to participate in a study to measure the amount of time spent screening Pap test slides and</p>

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		<p>workload assessment? This study will take place in 2014 and 2015.</p> <p>Q 47: Please provide an email address to contact you about the upcoming study. This email address will not be used for any other purposes.</p> <p>Q 48: In appreciation of your time in completing this survey, you will be entered into a drawing selecting 50 individuals to WIN a variety of prizes. Prizes include educational materials. If you haven't already, please provide your email below to be contacted if you win a PRIZE. As noted previously, email addresses will remain completely anonymous.</p> <p>Q 49: Please provide any additional comments about cytology workload or this survey.</p>
<p>Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory</p> <p><i>and</i></p> <p>Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist</p>	<p>Attachment C: Q3, Q6, Q12</p> <p>Attachment D: Q5, Q11</p>	<p>ADDING RESPONSE CATEGORY TO QUESTIONS</p> <p>-Don't Know to all questions</p> <p>-Added N/A response to now Q10, Q13, Q18, Q32, Q35</p>
<p>Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory</p>	<p>Attachment C: Q1</p> <p>Q2</p> <p>Q3</p>	<p>REFORMATTING QUESTIONS</p> <p>Q 2: include clinic/physician office to the regional laboratory option</p> <p>Q6: change CMS response option to "state surveyors for CMS"</p> <p>Q10: spell out FTE to full time equivalents and added to glossary terms. Also, added response categories to determine those labs that perform only</p>

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	<p>Q9, Q10, Q11</p> <p>Q12, Q13</p> <p>Q14</p> <p>Q16, Q17</p> <p>Q18</p>	<p>non-GYN cytology. The response categories are: Cytotechnologists (Total), Cytotechnologists who screen ONLY gynecologic slides, Cytotechnologists who screen ONLY non-gynecologic slides, Cytotechnologists who screen BOTH GYN and non-GYN slides, Pathologists who practice gynecologic cytopathology, Pathologists who perform primary screening of GYN slides</p> <p>Q 14, Q15, Q 16: Added skip logic, if answer no then the respondent is not asked Q15 and Q16</p> <p>Q 18, Q19: specified date</p> <p>Q20, Q21, Q22: Reformatted into 3 questions to improve clarity (What is the number of cases in each of the following interpretation categories that your laboratory reported in 2013? What percent of the negative cases were reclassified on review into the following diagnostic categories in 2013? Number of cases with corresponding LSIL+ or (CIN2) biopsy within 6 months of PAP?)</p> <p>Q44, Q45 Also asked of CT. reformatted one response into 2 response categories (1. Technical Supervisor determines that the CT is qualified to screen more, based on rescreening of at least 10% of negative cases interpreted as NILM and 2. Technical Supervisor determines that the CT is qualified to screen more, based on comparison of CT interpretation with technical supervisor's confirmation)</p> <p>Q23, Q24, Q25 Multiple questions to</p>

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Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist	Attachment D: Q3 Q5 Q11	<p>allow for as many CT as work in lab (Survey Monkey only allows 25 responses per question). Added column for per day and per hour (instead of one column), and the last 2 years.</p> <p>reformatted into multiple questions instead of 1 question:</p> <p>Q 28: According to your laboratory practice, is lunch included in your paid hours? (includes two columns with included? And how long is the lunch?)</p> <p>Q 29: According to your laboratory practice, are breaks included in your paid hours? (includes three columns with included? Number of breaks? Length of break?)</p> <p>Q30: According to your laboratory practice, are the following activities (where you are free from work related activities) included in your paid hours? (includes yes/no for continuing education, able to leave when maximum workload complete?)</p> <p>Q32: clarification language for response categories. New response categories: Total (GYN & non-GYN), GYN slides-Image-Assisted FOV only, GYN slides-Full Manual Review, Non-GYN/FNA</p> <p>Q35 clarification language for response categories. New response categories to be consistent with Q32: Total (GYN & non-GYN), GYN slides-Image-Assisted FOV only, GYN slides-Full Manual Review, Non-GYN/FNA</p>
Attachment C: Image-Assisted Cytology Workload Practices	Q4, Q5, Q6,	CHANGE QUESTION DATE Q11, Q12, Q13 from 2012 to 2013

Form	Current Question/Item	Requested Change
Survey-Laboratory		
Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory <i>and</i>	Glossary	<p>CHANGE QUESTION ORDER</p> <p>-moved glossary to the beginning of the survey instead of the last page both Attachment C and Attachment D</p>
Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist	Q6, Q7, Q8, Q9	Q39, 40, 44, 45 ask of both supervisors and CT, so changed order to put these questions at the end of the survey
Attachment C: Image-Assisted Cytology Workload Practices Survey-Laboratory <i>and</i> Attachment D: Image-Assisted Cytology Workload Practices Survey-Cytologist	Glossary	<p>DELETED PARTIAL ITEMS</p> <p>Removed FN, FP, TP from Glossary terms because they do not appear in any survey questions.</p>