METHODOLOGY FOR CONDUCTING AN INDEPENDENT STUDY OF THE BURDEN OF PATENTS-RELATED PAPERWORK

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1. INTRODUCTION

ICF International (ICF) is pleased to submit this report describing the methodologies we developed and recommend to conduct an independent study for the United States Patent and Trademark Office (USPTO or Agency) on patent-related paperwork costs.

The USPTO retained ICF to perform an independent study relating to the cost of paperwork, beginning with a report describing the methodologies for performing such a study. This report meets that requirement by recommending methodologies for addressing a wide range of topics about estimating the patent-related burdens imposed on the public as reflected in information collection requests (ICRs) under the Paperwork Reduction Act (PRA). This introduction describes the objectives of the overall study commissioned by the USPTO, the specific tasks to be completed under the study, and the organization of the remainder of this methodology report.

1.1 Overall Objectives for the Study

This report provides concise descriptions of the methodologies we recommend for conducting a number of specific inter-related analyses required by the Agency which together address three overall objectives for the study:

- 1. Develop an independent, publicly vetted, objectively-based estimate of the total cost of paperwork for patent applicants;
- 2. Develop recommendations for continued improvement in the accuracy of burden estimates made by the USPTO in the future;
- 3. Identify opportunities to reduce applicant burdens.

These objectives are to be met through a series of analyses specified by the USPTO to be performed independently by ICF, which are to provide impartial, fact-based results. The approaches described in this report for performing these analyses were developed independently by ICF, and are ICF's recommendations regarding the most efficient and effective ways to complete the analyses and to meet the overall objectives for the study.

1.2 Specific Analyses to be Addressed in the Study

This report addresses approaches for performing the study which is composed of the following inter-related analyses, as specified by the USPTO:

- 1. <u>Validate Reasons for Changes in Burden.</u> Evaluate the accuracy of the Agency's stated reasons for any significant changes in burden to applicants and the Agency's stated degree of discretion in imposing these changes.
- 2. <u>Compare the Accuracy of New versus Revised ICR Estimates.</u> Evaluate the relative accuracy of first-time estimates in ICRs for new requirements versus

estimates in subsequent ICRs that update previous estimates. Determine lessons learned for how to first estimate the burden associated with new requirements and how to best subsequently revise estimates for existing requirements.

- 3. <u>Estimate Total PRA Burden on Patent Applicants.</u> Review the Agency's previous estimates for burden to applicants, including identification and collection of any additional data needed, either for validation or for improving on these estimates. Identify lessons learned for making such estimates for this study and in the future. Estimate the total PRA burdens on patent applicants in light of a final rulemaking promulgated by the Agency, and lessons learned and new data from Analysis 2 and Analysis 3.
- 4. <u>Identify Potential Options for Reducing Applicant Burden.</u> During the course of each of the above analyses, be alert for possible options for reducing applicant burden, highlight these to the extent they are identified, and develop options for analyzing their potential.

1.3 Organization of this Report

The remainder of this report is organized as follows:

Section 2 describes the approach ICF used to develop the methodologies for performing the four inter-related analyses, including the principles and standards ICF adhered to, ICF's perspective on estimating the cost to those who bear the burden of complying with USPTO's requirements, and how the results of ICF's review of existing ICRs affected the development of the methodologies in this report.

Section 3 describes ICF's proposed methodology for each of the four analyses.

Section 4 discusses the expected timing for performing the four analyses.

Section 5 summarizes the key outputs from the study.

2. OVERALL APPROACH FOR DEVELOPING THE METHODOLOGIES

This Section describes ICF's overall approach for developing the methodologies for each of the four analyses to be addressed in the study, including:

- The principles and standards we applied;
- Our emphasis and view on the importance of adequate data, transparency, and appropriate granularity; and,
- Our review of existing burden estimates and the resulting implications for the methodologies.

The resulting specific methodologies for each of the required analyses are described in Section 3.

2.1 Working Principles and Standards

ICF established five working principles and standards for developing the methodologies for the four analyses listed in Section 1.

First, each of the analyses must comply with the USPTO's Information Quality Guidelines,¹ as appropriate. In part, this study itself contributes towards meeting the USPTO's meeting the requirements of its Information Quality Guidelines as they apply to the development of ICRs and related analyses. To a large extent the remaining working principles and standards below (as well as the next section on the importance of data, transparency, and granularity) further emphasize aspects of the USPTO's Information Quality Guidelines.

Second, the methodologies must provide transparent, authoritative estimates of cost. To accomplish this, the methodologies must maximize reliance on data and minimize reliance on judgment or assumptions. Further, to the extent feasible, all estimates (whether they are for the number of hours needed, the labor mix, the hourly rate, projections of number of applicants or applications affected, total cost, etc.) should be objectively-based and, at a minimum, the sources and methods for arriving at these estimates should be clearly explained and replicable as described in the USPTO's Information Quality Guidelines. Uncertainty should be explicitly addressed, such as through the use of ranges instead of point estimates, including assessment of its implications, such as through the use of sensitivity analysis or other methods.

Third, the methodologies should address the appropriate level of resolution or granularity. For example, in some cases, it is conceivable that USPTO-wide or applicant-wide costs estimates might not reveal important implications or conclusions

¹ <u>http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.html</u>.

that are specific to different arts, types of applicants or stages of the application process. Accordingly, separate estimates for different categories of applicants, applications, or stages of the application process should be developed when such variability has bearing for the USPTO's uses of the analysis.

Fourth, the methodologies should be comprehensive, addressing, to the extent feasible within the time and resource constraints of this study, all of the data, assumptions and analytic approaches that might be improved, as identified by public comment, the USPTO or ICF's evaluation.

Fifth, the analyses resulting from the application of the methodologies should meet the USPTO's requirements for the outputs of the study, providing:

- An independently developed and publicly vetted, transparent, data-based benchmark for the current cost of paperwork for patent applicants;
- A continuing basis for improving estimates in future ICRs and regulatory analyses;
- A useful input to the USPTO for evaluating potential reductions in burden to applicants.

2.2 Our Perspective on the Importance of Adequate Data, Transparency and Appropriate Granularity

ICF has more than 25 years of experience in providing regulatory support of all types for many federal agencies. In our experience, the magnitude of the cost of federal requirements borne by the affected parties is often represented by a diversity of cost experience (i.e., a distribution of cost across the affected parties) that can require great care to properly characterize. In these cases, we believe that often the best way to accurately estimate cost, to explain the basis for the estimates, to fully consider public comment on those estimates, and to demonstrate that subsequent estimates have appropriately considered all newly available data, is to explicitly develop and apply these distributions.

2.2.1 Explicit Analysis of Distributions

When estimating the total cost of a requirement, a common approach is to estimate the average cost of the requirement and multiply it by an estimate of the total number of those affected. However, the ability to accurately estimate the average, and to demonstrate the accuracy of that estimate, may vary greatly depending on the underlying distribution of cost across those who are affected. This is illustrated in Exhibit 2-1, which displays three types of distributions for the cost of a requirement

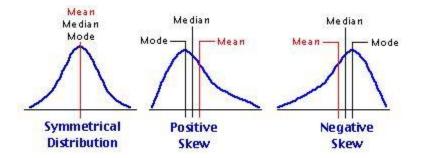


Exhibit 2-1: Illustrative Distributions and Associated Statistics

(x axis) and its incidence (y axis): symmetrical distribution, positively skewed distribution and negatively skewed distribution. Also shown for each distribution are statistics that are often used to describe what might be considered "typical": the mode (the most common value), the median (a midpoint in which half of the values are higher and half are lower), and the mean (average) for each distribution.

The simplest distribution is a symmetric distribution, in which the impact is relatively uniform (compared to the other types of distributions) across the affected population and where all of the key statistics are identical: i.e., the mode, the median and the mean are equal in value. Consequently, this is the easiest distribution to estimate and to develop statistics for. In these cases, to the extent that judgment-based estimates regarding typical cost are accurate (such as for the mode, the most likely cost), they also will provide a similarly accurate estimate for the average cost. Further, a similarly accurate estimate of the total cost is straightforward to obtain by multiplying the average cost by the total affected population.

However, in our experience, the underlying distribution of the cost of a requirement is often positively skewed ("right tailed"), with a long and fat tail. This means that a substantial portion of the affected population may have costs that are significantly greater than the "typical" cost (whether it is measured by the mode, median, or mean). While the data may be scarcer for the tail of the distribution and therefore more difficult to characterize, the tail can have a significant impact on the value of the average for the distribution. It is very difficult to use judgment alone to accurately estimate the average for skewed distributions - in these cases, judgment-based estimates of the average cost likely will tend to be biased toward the mode, which for positively skewed distributions will be less than the average value. In addition, a substantial portion of those who comment on USPTO's cost estimates may well be those who are more representative of the tail of the distribution and consequently understandably believe that the Office's estimate of average cost greatly underestimates cost, regardless of how accurate the Office's estimate of the overall average actually may be. This situation also can easily occur for negatively skewed distributions ("left tailed"), where a portion of the population experiences costs that are much greater than average, albeit a substantial portion of the population experiences costs that are much less than average. Further, when evaluating the impact of the costs, it often is important to give special attention to those who bear the highest costs rather than only the typical costs, because they may be more likely to experience the greatest impacts.

Consequently, especially where there is a diversity of cost experience across the affected parties, the explicit development and analysis of the distribution of cost is often the best way to:

- Accurately estimate total costs in a transparent way;
- Accurately estimate statistics regarding costs in a transparent way;
- Fully evaluate and properly incorporate input from public comment;
- Fully consider the impacts of the distribution of costs across those affected; and,
- Demonstrate that all data have been fully and adequately considered and reflected.

2.2.2 Understanding the Distributions

Often it is important to go beyond knowing what the distribution is, to also understanding why the distribution is skewed the way it is. For example, a skewed distribution for all applicants may reflect significant differences across different types of applicants and/or arts, in which applicants with certain combinations of characteristics tend to systematically experience higher or lower costs. By developing separate distributions for different categories of applicants and/or arts, the span of values for the distributions may narrow, and it may reveal cost patterns that might be important considerations for policy makers when making decisions regarding the design and applicability of requirements.

In addition, even for the same magnitude of burden, different categories of applicants (such as small entities, micro-entities and independent inventors) may be affected differently. This also can be an important consideration for policy makers when making decisions regarding the design and applicability of requirements.

2.2.3 Understanding the Parameters and Dependencies

The potential exists for any parameter that is being estimated to be more complex than it first appears. For example, it might seem that estimating the total number of hours to complete a task and estimating the average hourly rate associated with these hours would be straightforward tasks. However, the total number of hours may depend on the labor mix that is used (e.g., a specific combination of administrative staff, paralegals, attorneys, senior attorneys, etc.), and this labor mix may vary across applicants. The specific labor mix used likely would affect the associated average hourly cost. Thus, in this example, the two parameters (total hours and average hourly cost) are in fact dependent, and it is important to properly consider such dependencies both when making estimates and when understanding public comments and input regarding them. In addition, to follow through on the above example, it can be important to understand whether variability in labor mix reflects a matter of choice (perhaps the task can be accomplished through different labor mixes) or whether it reflects a difference of opinion regarding the necessity of a specific labor mix to accomplish the task (including the possibility that the labor mix must be tailored to reflect the characteristics of the application). Understanding which case may be operative can be important to properly estimating burden as well as fully understanding and making appropriate use of public comments and input.

2.3 Review of Existing Burden Estimates and the Implications for the Methodologies Recommended in Section 3

To develop an independent understanding of the existing burden estimates and of the issues that have been raised in public comment, the USPTO required ICF to review the current patent-related ICRs and analyses and the public comment on them. It was expected that this review would be especially helpful for the development of methodologies for estimating applicant burden.

This section lists the ICRs and FRN ICF reviewed, our approach to reviewing them, and the impact of that review on the development of the methodologies described in Section 3.

2.3.1 ICRs and FRN Selected for Review

ICF reviewed the current patent-related ICRs and a FRN, including analysis for the final rulemaking, applicable regulatory analyses, initial or final regulatory flexibility analyses, and the associated public comment. To compile a comprehensive, yet efficient and relevant set of materials for review, ICF selected patent-related ICRs, a FRN, related analyses and public comments issued as of 2005. The ICRs and FRN ICF reviewed are listed in Exhibit 2-2 and Exhibit 2-3.

2.3.2 ICF's Approach to Reviewing the Selected ICRs, FRN and Related Materials

ICF reviewed the ICRs, FRN and related materials listed in Exhibit 2-2 and Exhibit 2-3 from the perspective of assessing their implications for the development of the required methodologies in Section 3, while meeting the principles and standards as described in Section 2.1 and within the context of our perspective on the importance of data, transparency and appropriate granularity as described in Section 2.2.

In addition, to further assist in conducting a systematic and comprehensive review, ICF developed a list of topics areas that we also kept in mind as we reviewed the materials. While ICF's review was not limited to these topic areas, ICF considered these potential topics as likely to be addressed in the methodologies. The topic areas were divided into two categories: USPTO burden and applicant burden:

OMB Control Number	Information Collection Requests
0651-0063	Board of Patent Appeals and Interferences (BPAI) Actions
0651-0016	Rules for Patent Maintenance Fees
0651-0020	Patent Term Extension
0651-0021	Patent Cooperation Treaty
0651-0022	Deposit of Biological Materials
0651-0024	Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures
0651-0031	Patent Processing (Updating)
0651-0032	Initial Patent Applications
0651-0033	Post Allowance and Refiling
0651-0034	Secrecy and License to Export
0651-0035	Representative and Address Provisions
0651-0036	Statutory Invention Registration
0651-0058	Patent Prosecution Highway (PPH) Pilot Program
0651-0059	Patent Petitions Charging the Fee under 37 CFR 1.17(f)

Exhibit 2-2: Information Collection Requests Reviewed

Exhibit 2-3:	Federal	Register	Notices	Reviewed
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Federal Register Notice	Implementation Experience in 2008?	Information Collection Request
Proposed Rule Change for the Rules of Practice before the Board of Patent Appeals and Interferences in Ex Parte Appeals (72 FR 41472) (30Jul2007)		00XX
Rules of Practice before the Board of Patent Appeals and Interferences in Ex Parte Patent Appeals (73 FR 32937) (10Jun2008)		
Rules of Practice before the Board of Patent Appeals and Interferences in Ex Parte Patent Appeals; Delay of Effective and Applicability Dates (73 FR 74972) (10Dec2008)		

The topics for USPTO burden included the basis for:

- Forecasting workload;
- Estimating the hours of direct labor effort;
- Estimating the hourly rates associated with that effort;
- The USPTO overhead rate; and
- The level of resolution and subcategorization (e.g., by technology center or by the characteristics of the application).

The topics for applicant burden included the basis for:

- Forecasting total applicants affected;
- Estimating hours of labor and labor mix;
- Estimating hourly rates;
- Estimating total cost;
- Reliance on AIPLA survey data or other data;
- Reliance on judgment or assumptions;
- Level of resolution and subcategorization (e.g., by technology center or art unit, characteristics of the application, and characteristics of applicants including large, small, micro-entities and independent inventors); and
- Types of statistics estimated (e.g., mode, median, average, or "conservative").

2.3.3 Implications of the Review for the Development of the Methodologies

ICF initially anticipated that the review of the estimates and analyses in Exhibit 2-2 and Exhibit 2-3 would lead to the identification of specific estimates in each of the ICRs that would likely be the targets for the methodologies related to estimating applicant burden described in Section 3. However, as ICF's review proceeded, it became increasingly clear that such an approach would be too narrow and limited to meet all of the standards and principles for the study or to achieve all of its objectives, including fully meeting the USPTO's Information Quality Guidelines. Consequently, our review resulted in two sets of conclusions that drive the methodology we propose for estimating applicant burden as summarized below and described in more detail in Section 3.

Based on ICF's review, the requirements for applicants can be divided into two types that necessitate very different approaches when estimating their burden. First, there are existing requirements whose burden can be estimated and vetted using data from actual experience. Second, there are new requirements whose burden can only be estimated through projections which generally cannot be directly estimated or vetted

using actual experience. Our resulting approaches for estimating the burden for each of these two types of requirements are introduced briefly below and described in detail in Section 3. These two approaches address virtually all of the data, judgments and methods used in USPTO burden estimates, not just those which were the focus of public comment.

Estimates for Requirements that Already are Being Met

Estimates for existing burdens across all of the ICRs and analyses in Exhibit 2-2 often rely on data developed in surveys by the American Intellectual Property Law Association (AIPLA's biennial Report of the Economic Survey), as well as on some judgments by the USPTO. Consequently, the methodology described in 3.3.1 for developing applicant burdens proposes to assess:

- The applicability of the AIPLA survey data for use in preparing USPTO estimates of applicant burden;
- The appropriate ways in which AIPLA survey data should be used for USPTO's purposes; and,
- Alternatives for obtaining additional data to replace judgments or to address other data needs such as augmenting AIPLA survey data.

Upon completing these analyses, ICF will prepare an independent estimate of the overall applicant burden based on data that ICF has vetted. This also will provide a vetted foundation for future estimates by the USPTO as well as provide a basis for preparing guidelines and recommendations for the appropriate use of available data to make such estimates in the future. To the extent that judgment or assumptions still may be necessary (such as in cases where the desired data cannot be obtained), the manner in which such judgments should made and explained will also be addressed.

Estimates for New Requirements

For new requirements, it is necessary to make projections of burden, generally without the benefit of data representing actual applicant experience in meeting the requirements. As indicated in Exhibit 2-2 and Exhibit 2-3, these include requirements related to the Board of Patent Appeals and Interferences.

The public has commented on the USPTO's projections of burden, and ICF can use these comments in conjunction with ICF's own assessments to evaluate these projections using several techniques, as described in the methodology for Analysis 3 in Section 3.3. In addition, ICF will apply the lessons learned from the "retrospective" analysis of past burden estimates for new versus existing requirements as described in the methodology for Analysis 2 in Section 3.2.

While ICF expects that the results of the "retrospective" analysis of past burden estimates for new requirements, in combination with the public record of comments on these requirements, should provide a sufficient basis for performing this analysis, additional input from the applicant community in this area might provide further insights. Therefore, to more fully explore issues regarding the best ways to project cost for new requirements and to provide for elaboration on past public comment in these areas, we propose to explore the opportunity for additional input from the applicant community, as described in Section 3.3.2.

3. METHODOLOGIES FOR THE FOUR ANALYSES

This Section provides concise descriptions of methodologies for the following four analyses:

- 1. <u>Validate Reasons for Changes in Burden.</u> Evaluate the accuracy of the Agency's stated reasons for any significant changes in burden to applicants and the Agency's stated degree of discretion in imposing these changes.
- 2. <u>Compare the Accuracy of New versus Revised ICR Estimates.</u> Evaluate the relative accuracy of first-time estimates in ICRs for new requirements versus estimates in subsequent ICRs that update previous estimates. Determine lessons learned for how to first estimate the burden associated with new requirements and how to best subsequently revise estimates for existing requirements.
- 3. <u>Estimate Total PRA Burden on Patent Applicants.</u> Review the Agency's previous estimates for burden to applicants, including identification and collection of any additional data needed, either for validation or for improving on these estimates. Identify lessons learned for making such estimates for this study and in the future. Estimate the total PRA burdens on patent applicants in light of a final rulemaking promulgated by the Agency, and lessons learned and new data from Analyses 2 and 3.
- 4. <u>Identify Potential Options for Reducing Applicant Burden.</u> During the course of each of the above analyses, be alert for possible options for reducing applicant burden, highlight these to the extent they are identified, and develop options for analyzing their potential.

ICF has endeavored to develop methodologies for these analyses that are efficient while complying with the principles and standards described in Section 2. Consequently, some of the methodologies are designed to unwind in a staged manner, in which progress is assessed at the end of each stage, the implications for the next stage are evaluated, and adjustments to the approach for next stage are made as appropriate. Staged analyses are especially useful when surveys of various types may be needed, and the specific need for, feasibility of, and the design of the surveys depend on the results of the previous stage of the analysis. Thus, for example, while at this point ICF can anticipate that survey-related activities likely will be necessary, the actual need for them and their detailed specification must be developed during the course of the analysis itself.

ICF anticipates that most of these analyses can be completed within a 12-18 month period.

The following provides concise descriptions of the approaches that ICF recommends for each of the four analyses required by the USPTO. Once the overall study is initiated,

the first step in each analysis will be the development of a detailed work plan and associated schedule, to be submitted to USPTO for review and approval.

3.1 Analysis 1: Validate Reasons for Changes in Burden

The purpose of Analysis 1 is to validate the accuracy of the Agency's stated reasons for any significant changes in burden to applicants and the Agency's stated degree of discretion in imposing these changes. It is anticipated that this analysis will be completed within 12 to 18 months.

When there are changes in applicant burden, the Agency identifies the reason for the change and the degree of discretion it has in imposing these burdens. This information is a required input into the system that the Office of Management and Budget uses for managing regulations submitted by agencies. The Regulatory Information Service Center (RISC) of the General Services Administration (GSA) manages the system for OMB's Office of Information and Regulatory Affairs (OIRA). This system is called the <u>RISK and OIRA Consolidated Information System (ROCIS)</u>. ROCIS enables agencies to electronically submit regulations to OMB for review and comment.

ICF proposes to focus on the USPTO's inputs to the ROCIS system for all patent related ICRs (the ICRs listed in Exhibit 2-2) regarding the specified reasons for changes in burden and the Agency's degree of discretion. ROCIS requires the Agency to specify whether a burden increase or decrease is due to Agency discretion, including:

- Burden increases due to changing regulations, changing forms, miscellaneous actions or other; and,
- Burden decreases due to changing regulations, changing forms, cutting redundancy, using information technology, miscellaneous actions, or other.

If the burden change is due to a new statute, the type of mandate must be identified, such as US Code, Public Law, Statute at Large, Executive Order, or other. In addition, a short statement (up to 4000 characters long) must be provided explaining the reasons for any program changes or adjustments, how the reduction in burden was achieved, or why the increase in burden occurred.

ICF will develop criteria for when it is appropriate to assign each specific reason for explaining changes in burden, and for the degree of discretion. In addition, criteria will be developed for the information that should be included in the statement that explains the program change, how it is achieved, and why. The degree of discretion can be more nuanced and may need to be addressed in the explanation regarding the reason for the program change and how it is achieved. For example, although a program change may be required by statute so that the Agency has no discretion in making some type of change, the Agency may have had the discretion to develop options for meeting the statute's requirements and for selecting a specific option. ICF will review the resulting criteria with the USPTO and revise them as appropriate.

ICF then, in conjunction with the USPTO, will review the ROCIS inputs for the ICRs listed in Exhibit 2-2 to determine how well they meet the criteria, especially regarding explanation of the degree of Agency discretion.

Based on the results of the review, ICF will recommend appropriate steps for improving the future classification of reasons for change in burden in ICRs and for the Agency's degree of discretion.

3.2 Analysis 2: Compare Accuracy of New versus Revised ICR Estimates

The purpose of Analysis 2 is to evaluate the relative accuracy of first-time estimates in ICRs for new requirements versus the revised estimates in subsequent ICRs that update previous estimates. The results of this retrospective analysis also will provide a basis for gleaning lessons for how to better first estimate the burden associated with new requirements and how to best subsequently revise estimates for existing requirements. This analysis will be conducted in conjunction with Analysis 3 which evaluates the burden estimates for existing and new requirements, and will provide ICF's up-to-date, independent estimate of the total PRA burden on patent applicants. We anticipate that this analysis, along with Analysis 3, will be completed within 12 to 18 months.

The primary challenge associated with estimating the burden in ICRs associated with new requirements is that they typically are projections of burden associated with meeting requirements that have not been previously met. This is not always the case, however, because sometimes there can be relevant data gleaned from pilot programs or from voluntary activities that are similar to the requirements. In contrast, the estimates in renewed ICRs covering requirements that have been met can reflect data regarding actual burden experience so these estimates may be based more on data and less on projections. However, to some extent, even for existing requirements, some degree of forecasting may be needed to reflect potential trends such as improving productivity (which may decrease burden) or increasing application complexity (which may increase burden). Thus, to a significant degree, the relative accuracy of burden estimates for new versus revised ICRs may depend both on the specific requirements as well as the methodologies used in making the estimates.

3.2.1 Overall Approach

ICRs estimate annual burden for the next three-year period. Sometimes the estimates for the upcoming three-year period are new estimates for new requirements that will be met starting in the future, and sometimes they are updates of previous estimates for existing requirements that already are being met. In both circumstances, evaluating the relative accuracy of these estimates is best done in retrospect, comparing the estimated burdens to the actual burdens incurred using a consistent data source. For example, a new ICR prepared in 2003 for 2003-2005 would estimate the annual burden for a new requirement that first takes effect in 2003; and a subsequent renewal ICR in 2006 for 2006-2008 would revise the estimated burden for that requirement for these years. For

the burdens estimated in the two ICRs in this example, a consistent, appropriate data source over the period 2003-2008 could provide a reasonable basis for evaluating the relative and absolute accuracy of the initial and revised burden estimates in the ICRs.

As discussed previously in Section 2.3.3, the USPTO's estimates for existing burdens across all of the ICRs and analyses in Exhibit 2-2 and Exhibit 2-3 often rely on data developed in surveys by the American Intellectual Property Law Association (AIPLA's biennial Report of the Economic Survey). In the methodology for Analysis 3 (Section 3.3.1.), ICF proposes to validate the use of the AIPLA survey reports for the purposes of estimating patent-related burdens in the USPTO's ICRs and related analyses. As part of that effort, ICF also proposes to evaluate the appropriateness of using the AIPLA series of survey reports as a data source for evaluating the accuracy of the USPTO's burden estimates over time for this analysis (Analysis 2). The following assumes that Analysis 3 will determine that the AIPLA data base (or an alternative data source) is suitable and available for the purposes of assessing the accuracy of new versus revised ICR burden estimates. However, if needed, ICF is prepared to perform a separate, independent survey that will provide the data required for Analysis 2 as well as Analysis 3, as discussed in Section 3.3.1.

3.2.2 Steps in the Analysis

ICF proposes to perform this analysis in five steps as follows:

- 1. Identify the ICRs or components of ICRs that can be compared to data in the AIPLA survey reports as follows:
 - Review the ICRs in Exhibit 2-2 to identify those elements that are represented in both the current ICRs and in the most recent AIPLA biennial survey which collected data for 2008.
 - For those ICRs that have substantial components that can be compared to the AIPLA survey data, identify the initial ICRs in which those components are first estimated. For these initial ICRs, determine whether previous AIPLA surveys included data for these components.
 - The focus of the subsequent steps will be on those ICRs that have components that can be compared to AIPLA survey data as of the initial ICR burden estimates. ICF will assess whether this subset of ICRs is sufficiently representative to draw robust conclusions regarding the relative accuracy of the burden estimates in initial versus revised ICRs. If the subset of ICRs is not adequate, ICF is prepared to perform an independent survey as needed to adequately expand the number of ICRs (or ICR components) that are evaluated in the following steps.
- 2. Review the ICRs (or ICR components) and conduct research (e.g., interviews with USPTO staff) as needed to determine how the burden estimates were made for the original ICR and for subsequent revisions, and how public comments were

applied. In particular, assess the ways in which revisions were updated to reflect actual experience.

- 3. Compare the ICR (or ICR component) estimates of burden with the costs reported in the AIPLA survey data, including:
 - Comparing absolute values in specific years
 - Comparing percentage change in values over time
- 4. Evaluate the relative accuracy of the estimated burdens for new versus revised ICRs and the factors that explain any differences.
- 5. Review applicable public comments at the time for these ICRs (or ICR components) in light of the results of this analysis and assess in retrospect what the best application of these comments would have been to improve the accuracy of the burden estimates.
 - Identify lessons learned based on the above analyses:
 - For estimating burdens in ICRs for new requirements
 - For revising burdens in subsequent ICRs for existing requirements

Based on the results of this analysis ICF will identify steps for improving the burden estimating process to increase the accuracy of estimates for both new and existing patent-related USPTO requirements.

The results of this analysis will serve as an input into Analysis 3.

3.3 Analysis 3: Estimate Total PRA Burdens on Applicants

The purpose of Analysis 3 is to develop an independent, up-to-date estimate of the total PRA burden on applicants. It is anticipated that this analysis will be completed within 12 to 18 months.

This analysis will be accomplished by validating data sources, filling data gaps, and addressing issues that were raised in previous ICR estimates. This analysis will be closely coordinated with Analysis 2, which compares the accuracy of new versus revised ICR estimates, and will apply the lessons learned in estimating PRA burdens for both new and existing requirements.

As discussed in Section 2.3.3 (implications of ICF's review of the Agency's patent related ICRs and FRN for the development of the methodologies), the requirements for applicants can be divided into two types that necessitate very different approaches when estimating their burden or validating previous estimates. First, there are existing requirements for which burden can be estimated and vetted using data from actual experience. Second, there are new requirements for which burdens are typically

estimated through projections and generally cannot be directly estimated or vetted using actual experience.

The approaches for each of these two types of requirements are described in turn below, and their results will form the basis for estimating to the total burden to applicants.

3.3.1 Validating and Estimating Burden for Existing Requirements

By "existing" requirements, we mean requirements that were met by applicants in 2008, so that actual data can be obtained regarding the burden associated with meeting those requirements.

A source for many of the Agency's estimates for patent-related burdens is AIPLA's biennial Report of the Economic Survey. The survey is performed in odd-numbered years to collect data for the preceding year – thus the AIPLA's 2009 Report of the Economic Survey provides data for the calendar year 2008. The USPTO has relied on data from these AIPLA surveys to provide estimates of professional rates and total charges for some services, such as prior art searches, preparing divisionals, etc. The AIPLA survey generally provides a range of statistics for the data it reports (such as the mean, median, and first and third quartiles), and often reports separate statistics to reflect different degrees of complexity for the same activities. The AIPLA has conducted this periodic survey for several decades.

ICF concurs with the Agency's judgment that the AIPLA survey results often are likely to provide the most credible and up-to-date readily available data for estimating patent-related burdens in ICRs and in regulatory analyses. However, the AIPLA surveys and data have not been formally validated by the USPTO to assure that they are in fact appropriate for the specific purpose of estimating patent-related burdens in ICRs and regulatory analyses. It also is plausible that for the purposes of estimating burdens in ICRs and regulatory analyses, the Agency would need additional statistics or a broader representation of the data than are provided in the AIPLA survey reports to more completely characterize the full distribution of cost or to more finely subcategorize the results for USPTO's purposes, as discussed in Section 2.2 (the importance of data, transparency and appropriate granularity). In addition, previous AIPLA surveys have not collected all of the data that the Agency has needed to estimate burdens in ICRs, such as paraprofessional rates or applicant time.

Therefore, ICF proposes to validate the use of the data reported in the biennial AIPLA Report of the Economic Survey for the purposes of estimating patent-related burdens in the Agency's ICRs and regulatory analyses. This does not imply any criticism of the AIPLA surveys or their associated reports, but rather recognizes that the specific requirements for the data used in the Agency's ICRs and regulatory analyses might be different than those needed by AIPLA for its survey reports. Ideally, a one-time validation will suffice to assure the appropriate future use of the AIPLA survey reports by the USPTO. However, it may be possible that ICF will recommend that the Agency perform some type of periodic validation to assure appropriate use of data from future AIPLA surveys.

To validate the AIPLA survey data, ICF will seek to obtain a more detailed understanding of the AIPLA survey and its results. ICF may then seek to obtain additional data as needed to directly validate the AIPLA survey. Alternatively, ICF may determine that the most feasible, effective, and efficient approach for validating the AIPLA survey for the Agency's requirements is to perform a separate, independent survey that targets the specific data required by the Agency. These steps are discussed in greater detail below.

Initial Review of the AIPLA Survey

ICF will seek to work cooperatively with the AIPLA to develop a more in-depth understanding of the way in which it collects the data for the Report of the Economic Survey, and of the data itself. In doing so, ICF would comply with appropriate confidentiality terms or limitations on direct access to data as might be needed by the AIPLA. ICF likely will request the full data distributions for certain data elements to determine (a) whether the summary statistics in the AIPLA's survey reports are adequate for the Agency's purposes, and (b) whether (and how) these summary statistics should be adjusted for use in the Agency's ICRs or regulatory analyses.

This initial review will be coordinated with Analysis 2, which retrospectively compares the accuracy of new versus revised ICR estimates. For Analysis 2, ICF proposes to rely on AIPLA data across many surveys to track how burdens have changed over time. That analysis is likely to provide useful results for this analysis as well. For example, the evaluation of changes in burden over time (from one AIPLA report to the next) will help provide a basis for establishing procedures for properly escalating the costs in the AIPLA reports. This is relevant because the information in the AIPLA Reports often will be dated by one or two years for the USPTO's purposes (for example, in 2010 the data in the Report of the Economic Survey for 2009 will be two years old, and will need to be escalated).

Potential Additional Survey(s) and Analysis

Depending on the results of the initial review of the AIPLA survey, a limited follow-on survey or a separate survey may be needed to:

- Assess the importance of non-respondents and potential associated bias;
- Clarify the reasons underlying certain statistics;
- Obtain greater resolution or allow different aggregation;
- Develop a better understanding of the basis for respondent entries; and,
- Obtain additional data needed to estimate patent-related burdens for this study's purposes, but that are not currently adequately represented in the AIPLA survey.

These surveys may take the form of follow-on surveys of those who responded to the AIPLA survey as well as those who did not; or they may be separate surveys.

Alternatively, ICF may determine that the best approach for validating the Agency's use of the AIPLA survey data, as well as to augment it as needed, is to perform an independent survey that specifically targets all of the data required by the study. This would serve not only to provide the data needed for estimating the total PRA burden on patent applicants as described in Section 3.3.3 below, but also would serve as a basis for validating the use of the AIPLA survey data for Agency's purposes as well as serve as the basis for Analysis 2.

To the extent any surveys are needed, ICF will comply with all OMB and USPTO requirements for surveys. For example, some surveys require a 60-day Federal Register Notice, followed by a comprehensive submission regarding survey design and execution to OMB for its review and approval before they can be undertaken. ICF anticipates that the required surveys will be performed within 12 to 18 months, with the longer 18 month time frame reflecting the additional time that may be needed to complete and analyze the surveys that will be required for Analysis 3.

This analysis will provide four key outputs:

- Validation of the extent to which the Agency can use data from the AIPLA Reports of the Economic Survey to develop estimates of patent-related burdens.
- Guidelines for using the AIPLA Reports of the Economic Survey, including ways in which they should be adjusted or augmented for use in estimating patent-related burdens in ICRs and regulatory analyses.
- Options for the Agency to obtain improved up-to-date data on a continuing basis for estimating patent-related burdens. These options may include one-time or periodic surveys performed by the USPTO. It may also identify ways in which the AIPLA survey might be refined to enhance its appropriateness and usefulness for estimating applicant burdens in ICRs and regulatory analyses.
- Guidelines for assumptions and judgments when data cannot be obtained.

3.3.2 Validating and Estimating Burden for New Requirements

For the purposes of this methodology, "new" requirements are those requirements that were not met by applicants in 2008, although this may be extended to 2009 depending on the specific supplementary surveys that ICF conducts for this study.

Overall Approach

As discussed in 3.2, estimates for new requirements are necessarily projections of burden that often cannot be informed by actual direct experience. In these cases, estimates can be developed or evaluated using a number of techniques, including:

- Breaking the requirement down into component steps for which associated burdens can be estimated reasonably by experts;
- Applying data for related, comparable, or similar activities that provide perspective on the relative magnitude of the burden for the new requirement; and
- Simulating meeting the requirement.

Various combinations of these techniques have been applied in previous ICRs to first estimate the burden of requirements when they were new. The accuracy of these techniques will be examined in Analysis 2, which retrospectively compares the accuracy of new versus revised ICR estimates, and the lessons learned from that analysis regarding estimating burden for new requirements will be applied here. ICF also will carefully review the record of public comments regarding these estimates. In some cases, ICF may seek clarification from those who submitted comments in response to the FRN.

Based on the results of ICF's reviews and analyses, ICF will apply appropriate techniques to validate the estimates in existing ICRs for new requirements that have not been met in 2008.

Potential Opportunity for Additional Input from Applicants

While ICF believes that the record of public comment should be adequate to reflect the public input, it may be useful to provide for the opportunity to obtain additional input from the applicant community regarding applicant burden in an informal collaborative process. This also might provide a venue for ICF to elicit input on ways in which applicant burdens might be reduced as part of the assessment performed for Analysis 4. It is possible that topics related to any of the four analyses described in this section also might be included, initiated by either ICF or by the applicant community.

ICF proposes to explore the potential for establishing a practical, efficient, and timely means by which additional input from the applicant community might be obtained over the course of the study. For example, one possibility might be to establish a small core panel composed of representatives from several associations with broad representation (including, for example, organizations such as the American Intellectual Property Law Association, American Bar Association, Intellectual Property Association, and the National Association of Patent Practioners) that might serve as an interface with the applicant community. In this way, ICF might seek input regarding a specific set of questions or topics for which the core panel could either respond directly or the core panel could select representatives from amongst the applicant community that it believes are best able to address the topics at hand. While this could take the form of written interaction, it ideally also might include meetings with participants that are in the Washington DC area, augmented by conference calls for those who are not, to have the benefit of a more dynamic exchange of ideas and information. The goal would be to provide the opportunity for informed, representative input on specific topics from the applicant community, which might well take the form of a spectrum of opinion from the participants -- a consensus would not be required or expected.

If the applicant community is not interested in participating or if an appropriate, practical and timely method for collaboration is not feasible, then ICF will proceed with the analysis based on the public record as described above.

3.3.3 Estimate Total PRA Burden on Patent Applicants

ICF will estimate the total PRA burden on patent applicants based on the analyses, data collected, and lessons learned in Analysis 2 (comparing the accuracy of new versus revised ICR estimates, see Section 3.2) as well as in earlier portions of Analysis 3 (i.e., validating and estimating burden for existing requirements, as discussed in Section 3.3.1, and validating and estimating burden for new requirements, as discussed in Section 3.3.2).

In doing so, ICF will adhere to the working principles and standards described in Section 2.1 and will reflect the importance that ICF places on the use of data, transparency and appropriate granularity described in Section 2.2.

In addition to estimating the total PRA burden to applicants, ICF also will:

- Consolidate and translate the lessons learned in each of these analyses into step-by-step practical guidance for estimating PRA burden on patent applicants; and,
- Develop recommendations for continuing to assure and improve the basis for and accuracy of future burden estimates.

3.4 Analysis 4: Identify Options for Reducing Applicant Burden

The purpose of Analysis 4 is to identify potential options for reducing applicant burden. When performing each of the previous analyses, ICF will be alert to identifying potential opportunities for reducing applicant burden. Also, as the opportunities arise over the course of this study, ICF will elicit suggestions from applicants, associations and other experts.

As opportunities are identified, ICF will document them and inform the Agency. As required by the Agency, ICF will analyze the opportunities within 12 to 18 months.

4. TIMING

As described in Section 3, the study will be conducted over a 12-18 month period. The range for the length primarily reflects uncertainty regarding the need for surveys, survey design, the time it will take to obtain approval for them, and the time it will take to complete them.

5. SUMMARY OF KEY WORK PRODUCTS

Overall, the four analyses will provide:

- An independently developed and vetted, transparent, data-based benchmark for the current cost of the patent system to all participants;
- A continuing basis for improving estimates in future ICRs and regulatory analyses;
- A useful input to the USPTO for evaluating potential reductions in burden to applicants.

The specific work products for each of the 4 analyses will include:

Analysis 1 - Reasons for Changes in Burden

• Report on the Evaluation of Reasons for Changes in Burden and Degree of Discretion, including recommendations for future determinations.

Analysis 2 - Accuracy of New versus Revised ICR Estimates

• Report on the accuracy of new versus revised ICR estimates, including lessons learned regarding preparing new and revised ICR estimates

Analysis 3 - Total PRA Burden on Patent Applicants

- Report on the appropriate use of AIPLA survey data for ICRs and regulatory analyses, including use of additional or alternate sources of data
- Report estimating the total PRA burden on patent applicants
- Guidance on estimating burden for existing and new requirements

Analysis 4 - Potential Options for Reducing Applicant Burden

• Report identifying potential options for reducing applicant burden