

Dated: February 1, 2005.

**Betsey Dunaway,**

*Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.*

[FR Doc. 05-2487 Filed 2-8-05; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-05-0006]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To

request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-371-5976 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Statement in Support of Application for Waiver of Inadmissibility (0920-0006)—Extension “National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Section 212(a)(1) of the Immigration and Nationality Act states that aliens with specific health-related conditions are ineligible for admission into the United States. The Attorney General may waive application of this inadmissibility on health-related grounds if an application for waiver is filed and approved by the consular office considering the application for visa. NCID Division of Global Migration and Quarantine uses this application primarily to collect information to establish and maintain records of waiver applicants in order to notify the U. S. Citizenship and Immigration Services (USCIS) when terms, conditions and controls imposed by waiver are not met. NCID is requesting the extension of this data for 3 years. There are no costs to respondents except their time.

**ANNUALIZED BURDEN TABLE**

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Businesses or Organizations .....	200	1	10/60	33
Total .....	.....	.....	.....	33

Dated: February 2, 2005.

**Betsey Dunaway,**

*Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.*

[FR Doc. 05-2488 Filed 2-8-05; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**National Center for Chronic Disease Prevention and Health Promotion Conference Support Program; Correction**

A notice announcing the availability of Fiscal Year 2005 funds to award a Grant Agreement to Support Chronic Disease Prevention and Health Promotion Conferences, PA 05031 was published in the **Federal Register** on November 3, 2004, Volume 69, Number 212, pages 64057-64062. The notice is corrected as follows:

On page 64059, first column, under III.3 Other, Special Requirements, fourth bullet, delete the bullet that reads, “Applicants who do not submit a LOI will not be eligible to submit an application for review or funding.”

On page 64059, first column, under IV.2 Content and Form of Submission, Letter of Intent (LOI), first paragraph, delete the first and the fourth sentence that reads, “A LOI is required for this Program Announcement” and “If you do not submit a LOI, you will not be allowed to submit an application.”

On page 64060, first column, under IV.3 Submission Dates and Times, change to extend the LOI Deadline Date: Cycle B: February 14, 2005, delete the paragraph that reads, “CDC requires that you submit a LOI if you intend to apply for this program. Although the LOI will not be evaluated, and does not enter into review of your subsequent application, failure to submit a timely LOI will preclude you from submitting an application.” and replace with the following, “CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not

enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.”

Dated: February 3, 2005.

**William P. Nichols,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 05-2493 Filed 2-8-05; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Office of Community Services Funding Opportunity**

*Funding Opportunity Title:* Assets for Independence Demonstration Program.

*Announcement Type:* Grant-Initial.

*Funding Opportunity Number:* HHS-2005-ACF-OCS-EI-0053.

*CFDA Number:* 93.602.

*Category of Funding Activity:* Income Security and Social Services.

**Executive Summary:**

The Administration for Children and Families, Office of Community Services (OCS) will accept applications for financial assistance to establish and administer Assets for Independence (AFI) Projects. These projects assist low-income people in becoming economically self-sufficient. They do so by teaching project participants about economic and consumer issues and enabling them to establish matched savings accounts called Individual Development Accounts (IDA) in order to save for a first home, a business or higher education. Grantees must participate in an on-going national evaluation of the impact of AFI Projects and IDAs.

This is a standing announcement. It is effective until canceled or changed by the Office of Community Services. Applicants may submit applications at any time throughout the year. OCS will review and make funding decisions about applications submitted by any of three due dates: March 15, June 15 and November 1. (If a date falls on a weekend, the due date will be the following Monday.) For example, starting in mid-March annually, OCS will review all applications submitted November 2 through March 15. Starting in early June, OCS will review all applications submitted March 16 through June 15. And, starting in early November, OCS will review all applications submitted June 16 through November 1. Unsuccessful applicants may submit a new application in any succeeding application period.

Grantees must comply with terms of the Assets for Independence Act (AFIA) (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, as amended, Public Law 105-285, 42 U.S.C. 604 note) in submitting an application and administering an AFI Project.

The OCS Asset Building Web site (at <http://www.acf.hhs.gov/assetbuilding>) includes information about the AFI Program. The Web site presents a wealth of ideas and suggestions for developing and managing an AFI Project. In particular, it includes downloadable text of the AFI Act and a synopsis of grantee responsibilities imposed by the Act. It also features a downloadable guidebook, The AFI Project Builder that covers many topics and includes suggestions and best practices for planning, starting and implementing an AFI Project. Applicants can visit the website to obtain more in-depth information regarding the requirements for applying for and implementing an AFI Project.

**Priority Area 1****I. Funding Opportunity Description**

The Administration for Children and Families, Office of Community Services (OCS) will accept applications for financial assistance to establish and administer Assets for Independence (AFI) Projects. These projects assist low-income people in becoming economically self-sufficient. They do so by teaching project participants about economic and consumer issues and enabling them to establish matched savings accounts called Individual Development Accounts (IDA) in order to save for a first home, a business or higher education. Grantees must participate in an on-going national evaluation of the impact of AFI Projects and IDAs.

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The OCS Asset Building Web site (at <http://www.acf.hhs.gov/assetbuilding>) includes additional information about the AFI Program. The website includes a wealth of ideas and suggestions for developing and managing an AFI Project. In particular, it includes downloadable text of the AFI Act and a synopsis of grantee responsibilities imposed by the Act. It also features a downloadable guidebook, The AFI Project Builder that covers many topics and includes suggestions and best practices for planning, starting and implementing an AFI Project. Applicants can visit the website to obtain more in-depth information

regarding the requirements for applying for and implementing an AFI Project.

**Program Purpose and Scope**

The purpose of the Assets for Independence Program is to demonstrate and evaluate the effectiveness of asset-building projects that assist low-income people in becoming economically self-sufficient by teaching them about economic and consumer issues and enabling them to establish matched savings accounts called Individual Development Accounts (IDA). The program is demonstrating and evaluating the effects of AFI projects and IDAs in terms of increasing the economic self-sufficiency of low-income families; promoting savings for first-time homeownership, post-secondary education, and small business or micro-enterprise development; and stabilizing and improving families and communities.

OCS seeks to support innovative AFI Projects administered by national, State-wide, regional and community-based organizations. Organizations that may apply include, but are not limited to, Community Action Agencies; community development corporations; financial institutions such as banks, credit unions, and community development financial institutions; faith-based and community organizations; State and local government agencies; and other organizations such as marriage strengthening coalitions; service and fraternal organizations; schools, colleges and universities; and consortia or groups of organizations that collaborate to administer an AFI Project.

A broad range of organizations may be eligible for AFI Project funding, including the following:

- Organizations with projects that serve communities and groups that are less represented among the current AFI Projects such as residents of rural areas and Native American individuals or communities.
- Organizations with projects involving schools, colleges or universities to provide services to youth who are saving to attend higher education.
- Organizations with projects involving area businesses to provide services to the employees of those businesses. This may include local government agencies that seek to provide an IDA benefit for their employees.
- Organizations with projects involving the agency that manages the local welfare (Temporary Assistance for Needy Families—TANF) program; other offices that manage employment, education, and training

initiatives; and agencies that manage child support enforcement.

—Organizations with projects administered by a consortium or network of organizations including a lead organization and one or more subsidiary organizations. In this arrangement, a lead organization receives the OCS funding and administers the overall AFI Project including the financial accounting services for the project, while the subsidiary organizations provide services to project participants in a defined locality or a certain target population in a region, State, city or other geographic area. OCS believes such consortia or network arrangements may be particularly cost effective and efficient.

—Organizations with projects involving family strengthening coalitions and related organizations in an effort to integrate asset-building work with activities that promote healthy marriage and family formation. These activities may include, for example, communication skills training, marriage-oriented financial education, family budgeting, and marriage enrichment training. The goal for integrating asset building with healthy marriage projects is to link financial education with family budgeting abilities and marital communication skills that help to strengthen families and improve the communities in which families live.

OCS encourages and will provide preference to applicants that:

- Propose projects that will enroll participants from households with children;
- Propose projects that will enroll individuals residing within relatively well-defined neighborhoods or communities that experience high rates of poverty or unemployment; or
- Propose projects with a proportionally greater amount of funds committed from private sector sources.

## II. Award Information

*Funding Instrument Type:* Grant.

*Anticipated total priority area funding:* \$18,000,000.

*Anticipated number of awards:* 50 to 60.

*Average Projected Award Amount per project period:* \$327,273.

*Length of Project Periods:* Other.

*Explanation of other:* 5 year (60 months) project period with 5 year (60 months) budget period.

*Ceiling of Individual Awards per project period:* \$1,000,000.

*Floor on amount of individual awards per project period:* None.

## III. Eligibility Information

### 1. Eligible Applicants

State governments;  
County governments;  
City or township governments;  
Special district governments;  
Independent school districts;  
State controlled institutions of higher education;  
Native American tribal governments (Federally recognized);  
Public Housing authorities/Indian housing authorities;  
Native American tribal organizations (other than Federally recognized tribal governments); and  
Non-profits having a 501(c)(3) status with the IRS, other than institutions of higher education.

#### Additional Information on Eligibility:

Both Faith and Community-based organizations having 501(c)(3) status with the Internal Revenue Service are eligible to apply.

State, tribal, county, or local governments; school districts; public housing authorities; and other governments or agencies are eligible only as joint-applicants with a non-profit organization having 501(c)(3) status.

Low-Income Credit Unions and Community Development Financial Institutions are eligible only if they demonstrate a strong collaborative relationship with one or more local community-based organization(s) that seek to address poverty and the economic needs of community residents. Such community-based organizations may be any number of types of entities such as philanthropic foundations, community foundations, for-profit organizations, or non-profit organizations. If a non-profit, they are not required to have 501(c)(3) status.

Applicant Low-Income Credit Unions and Community Development Financial Institutions may be a subsidiary of or otherwise affiliated with a State, local or Tribal government, or any non-profit or for-profit organization.

Applicant Low-Income Credit Unions must submit official documentation that the National Credit Union Administration has designated the organization as such. For information about Low-Income Credit Unions, see <http://www.ncua.gov>.

Applicant Community Development Financial Institutions must submit official documentation that the U.S. Department of the Treasury has designated the organization as such. For information about Community Development Financial Institutions, go to <http://www.cdfifund.gov>.

Applications submitted by joint applicants, for example, by a State, local

or Tribal government agency and a non-profit organization, must clearly identify the organizations that are the joint applicants. The required Standard Form 424 "Application for Federal Assistance" must be signed by an authorized representative of the one joint applicant that will be responsible for grant administration and AFI Project implementation. The responsible applicant may be either the government agency or the non-profit organization.

Current AFI Project grantees may submit funding applications for new five-year projects. They will be reviewed competitively with all other applications.

Please see Section IV, for required documentation supporting eligibility and/or funding restrictions.

### 2. Cost Sharing/Matching

*Cost Sharing/Matching:* Yes.

#### Matching/Cost-Sharing

Grantees are required to meet a non-Federal share of project costs in accordance with Section 406(b) of the Assets for Independence Act. Grantees must provide at least 50 percent of the total approved cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share may be met by cash contributions only. Therefore, a project requesting \$350,000 in Federal funds (based on an award of \$350,000 per budget period) must provide a match of at least \$350,000 (50 percent of the total approved project costs). Grantees will be held accountable for commitments of non-Federal resources even if over the amount of the required match. Failure to provide the amount will result in disallowance of Federal funds. Lack of supporting documentation at the time of application will not impact the responsiveness of the application for competitive review.

Please note however that although applications that fail to provide such documentation at the time of application submission will not be barred from competitive review, matching/cost sharing will be used as an evaluation and/or preference criterion. Please see Section I. Funding Opportunity Description for a description of the matching/cost share requirement as a preference criterion. Please also see Section V.1 Budget and Budget Justification for the specific matching/cost sharing criterion that will be evaluated to support this preference.

### 3. Other

All applicants must have a Dun & Bradstreet Number. On June 27, 2003

the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal <http://www.grants.gov/>. A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1-866-705-5711 or you may request a number on-line at <http://www.dnb.com>.

Non-profit organizations applying for funding are required to submit proof of their non-profit status.

Proof of non-profit status is any one of the following:

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code.
- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.
- Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

(The Only Applicable Methods For the Assets For Independence Program Are the First and Second Bulleted Items. The Applicant Should Disregard the Other Areas Listed.)

When applying electronically we strongly suggest that you attach proof of non-profit status with your electronic application.

Private, non-profit organizations are encouraged to submit with their applications the survey located under

"Grant Related Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled, "Survey on Ensuring Equal Opportunity for Applicants," at: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

#### Disqualification Factors

Applications that exceed the ceiling amount will be considered non-responsive and will not be eligible for funding under this announcement.

Any application post-marked after 4:30 p.m. eastern time on the deadline date will not be considered for competition.

#### IV. Application and Submission Information

##### 1. Address To Request Application Package

Office of Community Services, ATTN: Assets for Independence Program, 370 L'Enfant Promenade, SW., #500 West, Washington, DC 20447, Phone: 202-401-4626, Fax: 202-401-5718, E-mail: [afiprogram@acf.hhs.gov](mailto:afiprogram@acf.hhs.gov), URL: <http://www.acf.hhs.gov/grants/open/HHS-2005-ACF-OCS-EI-0053.html>.

##### 2. Content and Form of Application Submission

###### Application Format

You may submit your application in either electronic or paper format.

To submit an application electronically, please use the <http://www.Grants.gov/Apply> site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. ACF will not accept grant applications via e-mail or facsimile transmission.

Please note the following if you plan to submit your application electronically via Grant.gov:

- Electronic submission is voluntary.
- When you enter the Grants.Gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline to begin the application process through Grants.Gov.

• We recommend you visit Grants.Gov at least 30 days prior to filling your application to fully understand the process and requirements. We encourage applicants who submit electronically to submit well before the closing date and time so that if difficulties are encountered an applicant can still send in a hard copy overnight. If you encounter difficulties, please contact the Grants.Gov Help Desk

at 1-800-518-4726 to report the problem and obtain assistance with the system.

- To use Grants.Gov you as the applicant, must have a DUNS Number and register in the Central Contact Registry (CCR). You should allow a minimum of five days to complete the CCR registration.

- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.

- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.

- Your application must comply with any page limitation requirements described in the program announcement.

- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grant.gov.

- We may request that you provide original signatures on forms at a later date.

- You may access the electronic application for this program on <http://www.grants.gov>.

- You must search for the downloadable application package by the CFDA number.

An original and two copies of the complete application are required. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, have original signatures, and be submitted unbound.

Private, non-profit organizations are encouraged to submit with their applications the survey located under "Grant Related Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled, "Survey on Ensuring Equal Opportunity for Applicants," at: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

###### Number of Pages in Application Package

Please number all application pages sequentially, beginning with the proposal abstract as page number one. Include page numbers for supplemental documents including appendices. Please do not include organizational brochures or other promotional materials, slides, films, newspaper clips, and so forth.

Applications should be thorough yet concise. We suggest up to 40 pages for the table of contents, project abstract

and project narrative, and any number of additional pages for required standard forms, assurances, certifications, disclosures, appendices, and supplemental documents.

#### Proof of Non-Profit Status

Non-profit organizations applying for funding are required to submit proof of their non-profit status.

Proof of non-profit status is any one of the following:

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code.
- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.
- Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

(The Only Applicable Methods for the Assets for Independence Program Are the First and Second Bulleted Items. The Applicant Should Disregard the Other Areas Listed.)

#### Proof of Low Income Credit Union Status

Applicant Low-Income Credit Unions must submit official documentation that the National Credit Union

Administration has designated the organization as such. For information about Low-Income Credit Unions, see <http://www.ncua.gov>.

#### Proof of Community Development Financial Institution Status

Applicant Community Development Financial Institutions must submit official documentation that the U. S. Department of the Treasury has designated the organization as such. For information about Community Development Financial Institutions, go to <http://www.cdfifund.gov>.

#### Standard Forms and Certifications

The project description should include all the information requirements described in the specific evaluation criteria outlined in the

program announcement under Section V Application Review Information. In addition to the project description, the applicant needs to complete all the standard forms required for making applications for awards under the announcement.

Applicants seeking financial assistance under this announcement must file the Standard Form (SF) 424, Application for Federal Assistance; Standard Form 424A, Budget Information-Non-Construction Programs; Standard Form 424B, Assurances: Non-Construction Programs. The forms may be reproduced for use in submitting applications. Applicants must sign and return the standard forms with their application.

Applicants must furnish prior to award an executed copy of the Standard Form LLL, Certification Regarding Lobbying, when applying for an award in excess of \$100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form, if applicable, with their applications (approved by the Office of Management and Budget under control number 0348-0046). Applicants must sign and return the certification with their application.

Applicants must also understand that they will be held accountable for the smoking prohibition included within Public Law 103-227, Title XII Environmental Tobacco Smoke (also known as the PRO-KIDS ACT of 1994). A copy of the **Federal Register** notice which implements the smoking prohibition is included with forms. By signing and submitting the application, applicants are providing certification and need not mail back the certification with the application.

Applicants must make the appropriate certification of their compliance with all Federal statutes related to nondiscrimination. By signing and submitting the applications, applicants are providing certification and need not mail back the certification form. Complete the standard forms and the associated certifications and assurances based on the instructions on the forms. The forms and certifications may be found at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

Please see Section V.1. Criteria, for instructions on preparing the full project description.

#### 3. Submission Dates and Times

##### Explanation of Due Dates

The closing time and date for receipt of applications is referenced above.

Mailed applications postmarked after the closing date will be classified as late.

**Deadline:** Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review referenced in *Section IV.6.*

Applicants must ensure that a legibly dated U.S. Postal Service postmark or a legibly dated, machine produced postmark of a commercial service is affixed to the envelope/package containing the application(s). To be acceptable of proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company from the applicant. Private Metered postmarks shall not be acceptable as proof of timely mailing. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

Applicants hand carried by applicants, applicant couriers, or by other representatives of the applicants shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., e.t., at the address referenced in Section IV.6., between Monday and Friday (excluding Federal holidays).

Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

ACF cannot accommodate transmission of applications by fax. Therefore, applications transmitted to ACF by fax will not be accepted regardless of date or time of submission and time of receipt.

**Late applications:** Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

**Extension of deadlines:** ACF may extend application deadlines when circumstances such as acts of God (flood, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases.

Determination to extend or waive deadline requirements rest with the Chief Grants Management Officer.

##### Checklist

You may use the checklist below as a guide when preparing your application package.

What to submit	Required content	Required form or format	When to submit
Project Abstract .....	See Section IV and V .....	Format described in IV and V .....	By application due date.
Project Narrative .....	See Section IV and V .....	Format described in IV and V .....	By application due date.
Budget Narrative/Justification .....	See Section IV and V .....	Format described in IV.2 and V.. .....	By application due date.
SF424 .....	See Section IV .....	Format described in IV .....	By application due date.
SF424A .....	See Section IV .....	Format described in IV .....	By application due date.
SF424B .....	See Section IV .....	Format described in IV .....	By application due date.
Certification regarding lobbying .....	See Section IV .....	Format described in <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	By Time of Award.
Certification regarding environmental tobacco smoke.	See Section IV .....	Format described in <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	By Time of Award.
Proof of Non-Profit Status .....	See Section III and IV .....	Format described in III and IV. .....	By Time of Award.
Proof of Low Income Credit Union Status (if applicable).	See Section III and IV .....	Format described in III and IV .....	By Time of Award.
Proof of Community Development Financial Institution Status (if applicable).	See Section II and IV .....	Format described in III and IV .....	By Time of Award.

#### Additional Forms

Private, non-profit organizations are encouraged to submit with their

applications the survey located under "Grant Related Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled, "Survey on

Ensuring Equal Opportunity for Applicants," at: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

What to submit	Required content	Required form or format	When to submit
Survey for Private, Non-Profit Grant Applicants.	Per required form .....	May be found at <a href="http://www.acf.hhs.gov/programs/ofs/form.htm">http://www.acf.hhs.gov/programs/ofs/form.htm</a> .	By application due date.

#### 4. Intergovernmental Review

##### State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

As of October 1, 2004, the following jurisdictions have elected to participate in the Executive Order process:

Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Kentucky, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, New York, North Dakota, Rhode Island, South Carolina, Texas, Utah, West Virginia, Wisconsin, American Samoa, Guam, North Mariana Islands, Puerto Rico, and Virgin Islands. As these jurisdictions have elected to participate in the Executive Order process, they have established SPOCs. Applicants from participating jurisdictions should contact their SPOC, as soon as possible, to alert them of prospective applications and receive instructions. Applicants must submit all required materials, if any, to the SPOC and indicate the date

of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2).

A SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade SW., 4th floor, Washington, DC 20447.

Although the remaining jurisdictions have chosen not to participate in the process, entities that meet the eligibility requirements of the program are still eligible to apply for a grant even if a State, Territory, Commonwealth, etc. does not have a SPOC. Therefore, applicants from these jurisdictions, or for projects administered by federally-recognized Indian Tribes, need take no action in regard to E.O. 12372.

The official list, including addresses, of the jurisdictions elected to participate in E.O. 12372 can be found on the following URL: <http://www.whitehouse.gov/omb/grants/s poc.html>.

A list of the Single Points of Contact for each State and Territory is included with the application materials for this announcement.

#### 5. Funding Restrictions

Grant awards will not allow reimbursement of pre-award costs.

Grantees must comply with terms of the Assets for Independence Act (AFIA) (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, as amended, Public Law 105-285, 42 U.S.C. 604 note) in submitting an application and administering an AF Project. Prior to award of project funds, OCS may communicate with potential grantees to ensure that the proposed projects conform to the AF.

Due to statutory limitations, OCS may not award any single AF Project grant of more than \$1,000,000.00.

#### 6. Other Submission Requirements

**Submission by Mail:** An applicant must provide an original application with all attachments, signed by an authorized representative and two copies. Please see Section IV.3 for an

explanation of due dates. Applications should be mailed to: Office of Community Services Operations Center, Assets for Independence Program, 1515 Wilson Blvd, Suite 100, Arlington, VA 22209, Attention: Administration for Children and Families, Office of Community Services, Assets for Independence Program.

**Hand Delivery:** An applicant must provide an original application with all attachments signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications should be delivered to: Office of Community Services Operations Center, Assets for Independence Program, 1515 Wilson Blvd, Suite 100, Arlington, VA 22209. Attention: Administration for Children and Families, Office of Community Services, Assets for Independence Program.

**Electronic Submission:** <http://www.grants.gov/>. Please see Section IV.2 Content and Form of Application Submission, for guidelines and requirements when submitting applications electronically.

## V. Application Review Information

### *The Paperwork Reduction Act of 1995 (Pub. L. 104-13)*

Public reporting burden for this collection of information is estimated to average 30 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

The project description is approved under OMB control number 0970-0139 which expires 4/30/2007.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The following are instructions and guidelines on how to prepare the "Project Summary / Abstract" and "Full Project Description" sections of the application. Under the evaluation criteria section, note that each criterion is preceded by the generic evaluation requirement under the ACF Uniform Project Description (UPD).

#### 1. Criteria

##### Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

##### Objectives and Need for Assistance

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s)

requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

##### Results or Benefits Expected

Identify the results and benefits to be derived.

##### Approach

Outline a plan of action that describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors that might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement. Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished.

When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates. If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF." List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

##### Evaluation

Provide a narrative addressing how the conduct of the project and the results of the project will be evaluated. In addressing the evaluation of results,

state how you will determine the extent to which the project has achieved its stated objectives and the extent to which the accomplishment of objectives can be attributed to the project. Discuss the criteria to be used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the project results and benefits are being achieved. With respect to the conduct of the project, define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

##### Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners, such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. If the applicant is a non-profit organization, submit proof of non-profit status in its application. The non-profit agency can accomplish this by providing: (a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate, (c) a statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status, (e) any of the items immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

##### Budget and Budget Justification

Provide a budget with line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and

other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF-424. Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

**Evaluation Criteria:** Members of proposal review panels will score applications based on the following criteria, some of which include factors and sub-factors.

#### Approach 50 Points

##### *Factor: Work Plan and Timeline (25 points).*

The extent to which the applicant provides a clear work plan for day-to-day operations, including responsibilities of the applicant and those of all participating organizations and financial institutions. The extent to which the work plan describes all significant activities anticipated for the entire 60-month project period such as: (a) Selecting and training key staff for the project; (b) Developing strong collaborations with key government agencies, faith-based organizations, and non-profit and for-profit organizations that will support the overall asset-building strategy; (c) Establishing and maintaining the Project Reserve Account; (d) Developing protocols for managing the Project Reserve Account including a system for allocating interest income for project administration and to project participants; (e) Establishing strong working relationships with one or more financial institution(s) that will participate in the project; (f) Reaching out to community residents, employers, and other key institutions about asset-building strategies in general and the IDA program in particular; (g) Recruiting, screening, and selecting project participants; (h) Determining the unique needs of each participant or group of participants including their needs for economic education, credit repair, and other assistance, as well as determining their particular strengths; (i) Providing economic education, credit repair, asset-specific information and other training or supportive services to participants; (j) Developing savings plans with participants and working with them to save accordingly; (k) Providing payments to project participants' IDAs as match for savings; (l) Establishing and maintaining IDAs for each participant including specific arrangements concerning the accounts with financial institutions or others; (m) Assisting participants who have difficulty completing the economic

education or abiding with the terms of their savings plan; (n) Ensuring that participants use IDAs only as appropriate, including for emergency expenses; (o) Ensuring that participants purchase an eligible, appreciable long-term asset within the program timeframes; (p) Providing follow-up assistance to participants, if needed; (q) Providing required financial and programmatic reports to OCS; (r) Participating actively in the national evaluation of the demonstration program including providing data and other information as required; and (s) Managing periodic internal program reviews concerning staffing, participant successes, and other issues to be addressed.

##### *Factor: Tax Services (3 points).*

The extent to which the applicant proposes to provide tax preparation assistance and assistance for claiming refundable tax credits such as Federal and State Earned Income Tax Credit and the Child Tax Credit for project participants as part of the overall program.

##### *Factor: IDA Match Rate (5 points).*

The extent to which the applicant proposes a clear and reasonable match rate or a menu of match rates for participants' IDAs that reflect the costs of eligible assets in the target community(ies).

##### *Factor: Innovation (5 points).*

The extent to which the applicant proposes any innovative strategies for vital program issues such as recruiting participants; working with local partners such as employers and financial institutions; enhancing financial education and financial literacy strategies; building partnerships with other organizations; using information technology, and so forth. The extent to which the applicant proposes a project that will be a component of other significant and comprehensive neighborhood change projects such as Empowerment Zone, Enterprise Community, Renewal Community projects, Weed and Seed projects, and so forth. The extent to which the applicant proposes a project that will integrate asset-building work with other related vital activities such as promoting healthy marriage and family formation as a means of achieving safety, permanency, and well-being for children and families.

##### *Factor: Partners/Collaborations (12 points).*

The extent to which the applicant provides a thorough and realistic plan for collaborating with an array of public and private organizations that will be involved in administering the project, describing the roles and responsibilities

of each, their capacity to participate in this project, and the process for recruiting additional partners throughout the project period. If the applicant is the lead organization of a collaborative or group of organizations that will administer the project, the extent to which the applicant clearly describes its capacity and experience in managing multi-agency projects and the roles and responsibilities of each participating organization. The extent to which the applicant presents a well conceived partnership including documentation of a strong relationship with one or more Federally insured financial institution(s) where the Project Reserve Account and participant Individual Development Accounts will be established and maintained. The extent to which the applicant will secure cost-share funds from private sector sources.

#### Organizational Profiles 17 Points

The extent to which the applicant provides clear and convincing information that it has the capacity and relevant experience in developing and operating successful programs or initiatives, including but not limited to efforts for addressing the causes and effects of poverty. The extent to which the applicant identifies a Project Director and staff with relevant experience including specific experience with the target population, working with financial institutions and partners, and implementing successful asset-building approaches and IDA programs.

#### Results or Benefits Expected 10 Points

The extent to which the applicant presents clear outcome and output statements that indicate progress in achieving the objectives (as stated in the Objectives and Need for Assistance criteria section) for delivering asset-building services and affecting the economic status of project participants.

#### Objectives and Need for Assistance 10 Points

##### *Factor: Goal and Objectives Statements (5 points).*

The extent to which the applicant presents clear program goal(s) supporting asset-building in general and IDAs in particular. The extent to which the applicant presents a small number of clear objective statements that describe anticipated targets or results of the project, such as the following three objectives that are linked to the national AFI Program goals: (1) The increase in the percentage of project participants who are homeowners; (2) The increase in the percentage of project participants

who acquire postsecondary education; and (3) The increase in the percentage of project participants who create or expand a micro-enterprise. The extent to which the program goal(s) and objectives relate to the needs for assistance and strengths identified. The extent to which the applicant's goal(s) and objectives reflect a commitment to the AFI Program and IDAs as tools for reducing poverty.

*Factor: Needs for Assistance and Strengths (5 points).*

The extent to which the applicant clearly identifies the needs and strengths of the target population and community(ies) or neighborhood(s), in terms of the geographic area, potential participant income, and other compelling information such as demographics, savings/assets acquisition, or other factors. The extent to which the applicant proposes a well-conceived project that will target households with children. The extent to which the applicant proposes a well-conceived project that will enroll individuals residing within relatively well-defined neighborhoods or communities that experience high rates of poverty or unemployment.

**Budget and Budget Justification 5 Points.**

The extent to which the applicant presents a clear and realistic budget and justification with reasonable amounts allocated for essential outcome-oriented activities such as program administration, economic education and other training and services for project participants. The extent to which the applicant presents clear evidence, in the form of letters or other documents, that the project will be supported with substantial amounts of non-federal cash funding (no less than the amount of the requested AFI Program grant).

**Evaluation 5 Points**

The extent to which the applicant presents a clear strategy for using an electronic information system to manage the overall project; to manage data about the status of project participants, their savings, and so forth; and to produce semi-annual and annual reports. The extent to which the applicant presents a clear commitment to participate actively in the national evaluation of the overall AFI Program by providing relevant and timely data to OCS and by collaborating with OCS on evaluation activities throughout the five-year project period.

**Project Summary and Abstract 3 Points**

The extent to which the applicant presents a clear one-page document that summarizes key features of the proposed project such as: goals and objectives; information about target community(ies); account structure and program design; partner organizations; locations of service sites; and non-federal funding and other support.

**2. Review and Selection Process**

Since ACF will be using non-Federal reviewers in the review process, applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget.

No grant award will be made on the basis of an incomplete application.

*OCS Evaluation of Applications*

Applications that comply with required procedures (e.g., those that are submitted timely by an eligible applicant) will be reviewed and rated by a panel based on the evaluation criteria stated in this announcement. OCS will make funding decisions based in part on the review panel scores and in part on other factors. The other factors may include: geographic distribution of AFI Projects; the applicant's record regarding timely and proper completion of federally funded projects; audit and investigative findings and issues; the applicant's progress in resolving any final audit disallowance on Federal funding; and information collected during pre-award site visits by OCS staff or representatives of OCS.

OCS encourages and will provide preference to applicants that:

- Propose projects that will enroll participants from households with children;
- Propose projects that will enroll individuals residing within relatively well-defined neighborhoods or communities that experience high rates of poverty or unemployment; or
- Propose projects with a proportionately greater amount of funds committed from private sector sources.

Please see Section V.1 for the specific evaluation criteria that relate to these preferences.

**Approved But Unfunded Applications**

In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case ACF has the option of

carrying over approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in later competition.

**3. Anticipated Announcement and Award Dates**

ACF anticipates to award funds in the third and fourth quarters of the fiscal year.

**VI. Award Administration Information**

**1. Award Notices**

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

**2. Administrative and National Policy Requirements**

- 45 CFR Part 74
- 45 CFR Part 92

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental) organizations.

**3. Reporting Requirements**

- Programmatic Reports: Semi-Annually
- Financial Status Reports: Semi-Annually

All grantees are required to submit semi-annual and annual program reports; grantees are also required to submit semi-annual and annual expenditure reports using the required financial standard report (SF-269) which can be found at the following URL: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

**VII. Agency Contacts**

**Program Office Contact:** James Gatz, Manager, Assets for Independence Program, Office of Community Services, 370 L'Enfant Promenade, SW., Suite 500 West, Washington, DC 20008, Phone: 202-401-4626, Fax: 202-401-5718, E-mail: [afiprogram@acf.hhs.gov](mailto:afiprogram@acf.hhs.gov).

**Grants Management Office Contact:** Barbara Ziegler Johnson, Office of

Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447, Phone: 800-281-9519, E-mail: [ocsgrants@acf.hhs.gov](mailto:ocsgrants@acf.hhs.gov).

### VIII. Other Information

Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: <http://www.Grants.gov>. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: <http://www.acf.hhs.gov/grants/index.html>.

Please visit the OCS Asset Building Web page at <http://www.acf.hhs.gov/assetbuilding> for additional information about this program. The Web site includes a wealth of ideas and suggestions for developing and managing an AFI Project. In particular, it includes downloadable text of the AFI Act and a synopsis of grantee responsibilities imposed by the Act. It also includes a downloadable guidebook, The AFI Project Builder, which includes many tips, suggestions and best practices for planning, starting and implementing an AFI Project. Applicants can visit the site for in-depth information regarding the requirements for applying for and implementing an AFI Project.

Applicants will be sent acknowledgements of received applications.

Dated: February 4, 2005.

**Clarence H. Carter,**  
Director, Office of Community Services.  
[FR Doc. 05-2512 Filed 2-8-05; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0021]

### International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled

“Q8 Pharmaceutical Development.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This draft guidance describes the suggested contents for the pharmaceutical development section in the quality module of a regulatory submission in the ICH M4 Common Technical Document (CTD) format. The draft guidance is intended to assist in the development of pharmaceutical studies that provide scientific understanding to support the establishment of specifications and manufacturing controls and serve as the basis for evaluating risk management over the life cycle of the product.

**DATES:** Submit written or electronic comments on the draft guidance by April 11, 2005.

**ADDRESSES:** Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

### FOR FURTHER INFORMATION CONTACT:

*Regarding the guidance:* Ajaz Hussain, Center for Drug Evaluation and Research (HFD-3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2847; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-435-5681.

*Regarding the ICH:* Michelle Limoli, Office of International Programs

(HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

### SUPPLEMENTARY INFORMATION:

#### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

During the July 2003 ICH meeting in Brussels, agreement was reached on a common vision and approach for developing an international plan for a harmonized pharmaceutical quality system that would be applicable across the life cycle of a product. This plan emphasizes an integrated approach to review (assessment) and inspection based on scientific risk management. One aspect of the plan was the establishment of an expert working