



# **INTERNATIONAL HARMONIZATION COUNCIL WORK PROCESS**

AIGA 078/12

***Asia Industrial Gases Association***

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## **1 Introduction**

### **1.1 Background to harmonization**

The industrial and medical gases industry has consistently grown at a faster rate than most industries and is increasingly international in scope. Major industrial and medical gas companies operate in all parts of the world. It is in the interest of enhanced safety, as well as improved efficiency, that standards and regulations are consistent and applicable wherever gases are produced, distributed, or used.

The International Oxygen Manufacturers Association (IOMA) Global Committee established the International Harmonization Council (IHC) to develop international standards for industrial and medical gases. The actions of the IHC are endorsed by the IOMA Global Committee and by leading industrial gas companies.

Gas industry Associations operating in Asia, North America, Europe and Japan have well developed safety standards and regulations, which are similar but not identical.

The IHC is working to develop international harmonized publications through four regional Associations, which are:

- Asia Industrial Gases Association (AIGA);
- Compressed Gas Association (CGA);
- European Industrial Gases Association (EIGA); and
- Japan Industrial and Medical Gases Association (JIMGA).

The Associations manage the creation and revision of harmonized publications through committees, task forces, or working groups populated by industry experts from Association member companies. In addition, some regional associations participate through the four core Associations. For example, the Australia and New Zealand Industrial Gases Association (ANZIGA), the Middle East Gases Association (MEGA), and the Southern Africa Compressed Gases Association (SACGA) participate as corresponding members via EIGA.

### **1.2 Intent of harmonization**

When developing a new publication or revising an existing one (referred to as a "project"), IHC member Associations should compare their libraries to identify areas where there is an overlap or a gap in the scope of existing publications. It is the intent of this process that member Associations should avoid duplication of effort and/or conflicting standards and recommendations in these publications.

Projects proposed for harmonization are assessed, approved, and prioritized by the IHC according to risk and impact to the industry (see Annexes A and B). These projects result in publications that shall be adopted for use by all participating IHC Association member companies. Members shall adopt a harmonized publication unless it can be shown that the publication is not appropriate in a specific region.

The Associations review each other's publications during the harmonization work process to determine the degree of conflict and/or similarity. When a harmonized publication cannot be agreed upon, every attempt shall be made to resolve the issues and document the differences.

### **1.3 Benefits of harmonization**

The safety of industry employees, end users of industrial and medical gases, and the general public have always been foremost among the business objectives of the industry. To further advance safety goals, it has become increasingly important and beneficial for the industry to share safety practices as well as to reduce the variability in safety standards and operating practices.

Benefits of harmonization include:

- The industrial gas industry will be safer by sharing and utilizing best practices for safe operation internationally.

- Reducing confusion and enhancing compliance through the development of non-conflicting common industry positions.
- Local and regional companies can access the experience, research, data, and consensus opinion of the industry's leading experts.
- Qualified resources to work on publications are always limited. Developing and implementing harmonized publications use experts' time efficiently by eliminating duplicate regional efforts.
- International industry consensus publications are useful in limiting ineffective and/or conflicting regulations. It is more efficient to proactively self-regulate with harmonized publications.
- A common approach to safety and operating practices increases standardization, which in turn reduces costs and improves operating efficiency.

#### **1.4 Code of conduct**

The IHC established a basic code of conduct for all participants to support the harmonization process:

- Find an industry position among the participating Associations;
- Defend that position in external committees/meetings (e.g., with regulators); and
- If any Association or member company deviates from that position they should, whenever possible, inform the other involved Associations prior to the external committee meeting.

## **2 Harmonization overview**

### **2.1 Harmonization principles and requirements**

The intent is to have harmonized publications that are identical in purpose and scope and have no conflicting operational practices. There will be regional differences, such as those mandated by regulations.

Examples of differences that may be expected in regional versions:

- local/regional regulatory requirements;
- substitution of equivalent regional references;
- units of measurement;
- spellings;
- terminology; and
- publication formatting.

## **3 Roles and responsibilities**

The roles and responsibilities for the IOMA Global Committee and the IHC have been defined by the IOMA Global Committee and are listed below. The IHC Associations have further extended the definitions to include the roles and responsibilities of the Associations, member companies, and committees, task forces, and working groups. For the harmonization process to work smoothly, all involved parties need to understand their part in the overall process. See Annex C for the organization structure.

### **3.1 IOMA Global Committee**

The role of the IOMA Global Committee is to oversee the harmonization process. The responsibilities of the IOMA Global Committee include:

- Review and guide the international harmonization of gas industry publications.
- Review new harmonization project proposals and authorize as new active projects.
- Monitor progress of all active projects.

- Ensure alignment within member companies to facilitate harmonization.
- Review membership of the IHC.
- Ensure sufficient IHC work resources.
- Provide recognition of working members.
- Review nominees and select the IOMA Harmonization Award recipient. See Annex D.

### **3.2 International Harmonization Council (IHC)**

The role of the IHC is to manage the harmonization process. The management responsibilities of the IHC include:

- Reviewing, assessing, and prioritizing the harmonization project proposals.
- Preparing recommendations for the IOMA Global Committee on what projects should be made active.
- Reviewing progress of projects within the harmonization initiative and identify areas of concern.
- Preparing reports for the IOMA Global Committee on the progress of active projects.
- Reviewing effectiveness of the harmonization work process and making any necessary adjustments.
- Defining parameters of a harmonized publication (e.g. purpose, definitions, scope, prescriptive/performance approach).
- Preparing a list of IOMA Harmonization Award nominees for submission to the IOMA Global Committee (see Annex D for criteria).

The IHC shall meet at least twice per year. The meetings are hosted by each Association on a rotating basis. The meeting locations shall also rotate between Association locations. Additional meetings may be scheduled if required by specific circumstances. The IHC agrees to the meeting schedule.

The responsibilities of the hosting Association include:

- Issuing the meeting invitation including location and logistics details.
- Reserving meeting space for the event.
- Chairing the meeting.
- Scheduling the IHC pre-meeting to review items of interest at least one month prior to the meeting (see agenda format in Annex E).
- Issuing the meeting agenda one month before the meeting (see agenda format in Annex E).
- Reviewing the meeting minutes.
- Circulating the draft minutes to IHC members for comment within 4 weeks of the meeting.

NOTE – The IHC Administrator provides assistance with some of the hosting Association responsibilities. See section 3.3.3.

### **3.3 Associations**

The role of all participating IHC Associations is to support the harmonization process. The responsibilities of all IHC Associations include:

- Participating in the IHC.
- Managing the harmonization work process.
- Developing and improving Association work processes in support of harmonization.
- Communicating with internal committees, councils, or working groups.

- Forming or assigning committees, working groups, or participants for joint working groups to accomplish harmonization work.
- Maintaining publication management of change processes that effectively document justifications for decisions on proposed changes. See Annex F.
- Submitting potential harmonization projects for consideration by the IHC. See Annex G.
- Hosting IHC meetings on a rotating basis (see section 3.2).

### **3.3.1 IHC Association Representatives**

The role of IHC Association Representatives is to represent their Association during IHC meetings. The IHC member representatives who may attend IHC meetings include:

- AIGA Secretary General, CGA President and CEO, EIGA General Secretary, JIMGA Executive Managing Director. These participants also represent their Associations on the IOMA Global Committee.
- AIGA Technical Committee Liaison, CGA Technical Director, EIGA Deputy General Secretary, JIMGA's representative from the Technical/Safety Council, representing their Associations as Technical Liaisons.
- Representatives from AIGA's Technical Committee, CGA's Standards Council, EIGA's Industrial Gases Council, and JIMGA's International Council.

Associations should ensure continuity of representation at IHC meetings. Additional Association representatives may be invited to participate subject to the agreement of the IHC Associations.

### **3.3.2 Association Technical Liaisons**

The role of Association Technical Liaisons is to provide technical support for the IHC projects and to liaise between the IHC and Association members. The responsibilities of the Association Technical Liaisons include:

- Functioning as technical liaison between IHC Associations.
- Managing harmonization process within their Association.
- Coordinating harmonization efforts with their technical liaisons.
- Monitoring progress of harmonization projects and identifying and reporting delays to the project schedule.
- Providing a liaison status report at IHC meetings.

### **3.3.3 IHC Administrator**

The role of the IHC Administrator is to provide administrative support for the harmonization process. The responsibilities of the IHC Administrator include:

- Assisting with preparation of meeting materials and providing webconference information for the IHC pre-meeting.
- Assisting with the preparation of meeting materials for the IHC meeting.
- Recording the meeting minutes.
- Recording updates to the IHC Project Report (PR).
- Updating the IHC Project Summary Table during each IHC meeting.
- Providing the draft minutes to IHC members for review and circulation for comment.
- Preparing the draft minutes, IHC Project Report (PR), and IHC Presentation to the IOMA Global Committee for submission by CGA or EIGA representatives in IOMA GC, 4 weeks before the IOMA meeting.



### 3.3.4 Project Lead Association

The role of the Project Lead Association is to manage the work process for individual IHC projects. The responsibilities of the Lead Association include:

- Coordinating the project with all participating Associations.
- Scheduling and/or hosting meetings to achieve progress on the project.
- Ensuring that comments from other Associations are reviewed and resolved.
- Approving other Associations' final regional versions of a project for publication.

See Annexes H, I, J, and K for the Lead Association's process.

There may be occasions where two Associations decide to jointly manage a project; in such cases one Association shall assume the Lead Association role for administrative purposes. The Association identified as the lead for administrative purposes will be the first initial listed in the IHC project number (i.e., if AIGA and JIMGA are jointly managing a project but JIMGA is identified as the administrative Lead Association, the project number would be A-1234-2011-JA).

### 3.3.5 Association Committee/Working Group Liaisons

The role of Association Committee/Working Group Liaisons is to monitor the activities of related groups in other IHC Associations. The responsibilities of the Association Committee/Working Group Liaisons include:

- Reviewing any agendas, minutes, or activity reports from other related groups.
- Reporting on other related group activities to Association Committee/Working Group.
- Providing updates on any related work activities to other related groups.
- Attending the meetings of other related groups when possible.

Member Association committees, working groups and councils should be matched by similar areas of responsibility. This is to include overall scope as well as specific publication responsibility.

### 3.3.6 Committee, Working Group, or Joint Working Group

The role of Committee, Working Group, or Joint Working group members is to provide the resources and expertise to complete IHC projects. The responsibilities of the group of Association members working to create or adopt the harmonization project include:

- Understanding the harmonization processes.
- Liaising with experts from other Associations.
- Representing an internally aligned company position, and/or
- Representing an internally aligned Association position.
- Being flexible and consider other approaches and ideas when safety is not compromised.
- Researching existing industry and company publications and/or positions.
- Providing timely input in accordance with harmonization schedule.
- Attending harmonization project meetings.
- Developing new drafts or revising the content of existing projects.
- Reviewing and reaching a consensus on proposed changes to new or revised publications.

### **3.3.7 Association Member Companies**

The role of Association Member Companies is to support the ongoing harmonization of industry publications. The responsibilities of all participating member companies include:

- Developing internal company alignment on harmonization projects.
- Providing resources for Association participation and harmonization projects.
- Supporting necessary travel for participation.

## **4 Harmonization work process**

### **4.1 Sources of harmonization projects**

#### **4.1.1 Adoption of existing Association publications**

When a publication exists in an Association's library and is accepted by other IHC Associations as a harmonization project, it shall be revised to allow international use.

#### **4.1.2 New harmonized publication**

When a gap in Associations' libraries is identified or new material becomes available for harmonization, a new publication may be developed.

#### **4.1.3 Merging similar Association publications**

When associations have similar publications, those positions may be merged to create a single harmonized position.

#### **4.1.4 Harmonized best practices publications**

When associations have similar publications, but they cannot be identical due to differences in regional regulations, a proposal can be made to develop a harmonized publication that captures only industry best practices (often as performance-based measures rather than prescriptive positions).

For example, a best practices publication may include:

- a general overview of a specific topic (i.e., general discussion of equipment used, basic operational procedures that are similar internationally);
- performance based objectives; and
- discussion of the basic safety requirements, outside of what is required by regulation, that can be agreed to by all participating regions.

Following the harmonization of a best practices publication, individual Associations may develop prescriptive non-harmonized publications to provide further guidance on specific regional practices. These publications shall not conflict with the harmonized best practices publication.

#### **4.1.5 Revision of a harmonized publication**

All participating Associations shall be notified by the Lead Association prior to the revision of a harmonized publication; harmonized publications shall not be unilaterally revised without approval by the IHC. If an Association revises a publication unilaterally with the approval of the IHC, they shall report to the IOMA Global Committee that the project is no longer harmonized.

NOTE – Regional publications revised to include new or changed regulatory requirements are not considered unharmonized, but re-publication shall be approved by the project Lead Association and reported to other IHC Associations.

The proposed change cutoff date to revise a harmonized publication should be scheduled six years after the previous edition's proposed change cutoff date (or previous Lead Association publication date when one is not available). The lead Association for the original project shall remain as the lead for any subsequent revisions,

unless the lead Association relinquishes that role and a new Association volunteers to become the lead. A WIR is needed for a revision. Approximately 12 months prior to the proposed change cutoff date, the lead Association will announce the proposed change cutoff date to all participating Association Technical Liaisons. After the proposed change cutoff date, the lead Association shall review the changes received and make a recommendation regarding the next steps for the revision. The lead Association shall submit a WIR indicating that the publication should be revised as scheduled, reaffirmed with no changes, or delayed by up to 2 years for revision.

Harmonized publications should only be revised when technical changes are necessary to correct or enhance the accuracy and/or effectiveness of a publication, or to introduce new requirements. If no technical changes are needed at the revision date, the publication may be reaffirmed by a vote of all participating Associations, or the revision date may be extended by up to 2 years.

If there is a compelling safety reason or discovery of a technical error in a harmonized publication, the revision cycle may be shortened. Requests for a shortened revision schedule shall include justification for shortening the revision cycle and recommended new revision date. A majority of participating Associations shall approve the shortened revision cycle. Upon approval of a shortened revision schedule, the lead Association shall announce the new comment close date to all Associations.

The revision of a harmonized publication can follow any of the processes described in section 4.3.

## **4.2 Project work processes**

There are three principle ways to develop harmonized publications; the method to be used for a harmonization project is recommended by the proposing Association and agreed by the IHC.

Members of all participating Associations are permitted to participate in publication development and review. Each company represented shall designate one participant to serve as the voting representative for their organization. Additional representatives from each company, including representatives from international locations, may attend, but shall not be permitted to vote unless designated as a proxy for an absent voting representative. For example, a company with participants in AIGA, CGA, EIGA, and JIMGA would be permitted one voting representative even though they may be separate entities in different parts of the world.

### **4.2.1 Joint Working Group (JWG)**

The Joint Working Group (JWG) is preferred, especially for new publications. Once the publication is produced, it is typically approved much faster, because more input is obtained early in the process.

In this method, a JWG is formed that includes representatives from all interested Associations. The Lead Association shall announce the formation of a JWG to all participating Associations, and hosts the first meeting of the JWG. Members of the JWG work together to develop a new publication or provide comments to an existing publication.

When the draft or revision work is completed, the Lead Association distributes the draft publication to all participating associations for comment. At that time, the Lead Association also establishes a comment close date; after the close date, no new comments may be submitted. After comments are received from all participating associations, the JWG reviews and resolves those comments.

Once the comments are reviewed and resolved, the publication and reasons for the decisions on changes are sent to the regional Associations' governing councils for approval and publication in accordance with their procedures. The Lead Association approves all regional versions of a harmonized project prior to publication by any participating associations.

See Annex L for the JWG process.

### **4.2.2 Lead Association with JWG review of comments**

In this method, the Lead Association works independently to draft a new harmonized publication, or accepts comments on an existing publication from individual associations. The Lead Association distributes the draft publication to all participating associations for comment. At that time, the Lead Association also establishes a comment close date; after the close date, no new comments may be submitted. After comments are received from all participating associations, the JWG reviews and resolves those comments.

Once the comments are reviewed and resolved, the publication and reasons for the decisions on changes are sent to the regional Associations' governing councils for approval and publication in accordance with their procedures. The Lead Association approves all regional versions of a harmonized project prior to publication by any participating associations.

#### **4.2.3 Lead Association without JWG review of comments**

In this method, one Association takes the lead in developing the publication, using its own procedures. It completes and publishes the publication. Other Associations then review the publication, comment, and propose changes. The Lead Association then accepts or rejects the proposed changes. The reasons for decisions on proposed changes are sent to the other Associations who are harmonizing the publication.

Once the comments are reviewed and resolved, the publication and reasons for the decisions on changes are sent to the regional Associations' governing councils for approval and publication in accordance with their procedures. The Lead Association approves all regional versions of a harmonized project prior to publication by any participating associations.

This process is viable only when the harmonization topic is relatively straightforward or when an Association wants to adopt an existing publication from another Association, however, the difficulty in coordinating regional versions and ensuring that comments from all Associations are reflected in each regional version can create significant delays and re-work for the participants.

### **4.3 Identification of future harmonization projects**

Each Association shall have an internal process to identify potential projects and evaluate their validity for proposal as future harmonization projects. Committees and working groups are asked to identify potential harmonization projects and are asked to provide an assessment of the urgency of issue, potential risk/risk involved, and impact or potential impact.

On a continuous basis each Association shall review publications that will be created or reviewed/updated in the next year. They shall review the respective libraries to see which publications are overlapping in scope. The technical liaisons shall submit any topics identified as potential harmonization projects for review by the IHC at its next meeting.

Each Association presents projects for review and approval by their governing councils. The project proposals which are approved are then sent by the proposing Association to the IHC for consideration.

### **4.4 Proposal of future harmonization projects**

Association members and/or staff shall use the Work Item Request (WIR) form, shown in Annex A, to propose new projects. The form is important to ensure the consistency of information provided so the Associations and the IHC can better judge the relative merits of the proposal. The proposing Association is responsible for completing all fields of the WIR.

On the WIR, the proposing Association should indicate which Association will serve as the Lead for the project. The Lead Association is typically the owner of the original publication or proposer of a new publication topic.

Before submission to the IHC for consideration, the WIR should be approved in accordance with the Association's procedures for new work requests.

### **4.5 Evaluation and approval of Active Projects**

Harmonization work item requests (WIRs) and the proposing Association's recommended risk based scores (see Annex B) are submitted to the IHC by the Association's Technical Liaison. The selected projects are shared in advance of the next IHC meeting to allow a minimum of 90 days for review and approval or rejection by the other Associations. This may be reduced upon agreement to accommodate individual association work processes or short notice, high priority projects. Each Association's IHC representative should be authorized to either approve or reject projects at the next IHC meeting.

Upon receipt of a WIR, the IHC reviews the proposal to determine whether it should be harmonized. The scores of high, medium, or low given to each proposed topic in the categories of urgency of issue, potential risk/risk involved, and impact or potential impact are reviewed.

If the proposal is accepted, the IHC shall evaluate the risks and industry impact using the risk scoring criteria in Annex B. Future projects will be prioritized based on the total risk assessment score and availability of resources to complete work on the topic.

The projects proposed to become active are presented during the IHC report at the next IOMA Global Committee meeting for final approval. If approved, the project is assigned an IHC project number, as shown in Figure 1, for tracking purposes.



**Figure 1—IHC Project Number Examples**

Each project receives a project status designation, which is the first letter of the IHC project number. Projects are classified as:

- A: projects that are currently active and included on the IHC PR;
- R[x]: revision projects that are currently active and included on the IHC PR, with [x] designating the number of times a project has been revised and the project number remaining the same as the original; or

NOTE – Future projects are not assigned an IHC project number, but are documented (with relevant scoring information) in the IHC Future Projects List.

## **5 Harmonized publication writing guidelines**

For more complete information on harmonized publication writing guidelines, please see *IHC, Harmonization Style Manual*.

### **5.1.1 Titles**

It is important to avoid using the term “code” in a title and within the publication (e.g., code of practice). While in some regions this is seen as best practice, in other regions this implies a mandatory requirement or legal document. When the term code is used in an existing document, associations may replace it with publication.

### **5.1.2 Definitions**

Several words have specific definitions (see Annex M). Include a section on definitions, ensuring that all key terms are agreed upon and defined. It is recommended to use definitions from existing industry publications where possible, e.g., ISO 10286, UN Model Regulations and NFPA.

### **5.1.3 Use of existing publications**

Whenever possible, an Association's existing publication should be used as a basis or starting point. Harmonization of an existing position should require fewer resources than those needed to develop regional publications and reconcile these later.

### **5.1.4 References**

Use references as needed. It is better to refer to an existing publication than repeat the information in a publication. Exceptions can be made if the information to be included is short and unlikely to change in the future. Publications that can be referenced include:

- industrial gas Association publications;
- regulations; and
- other codes or standards from recognized authorities (i.e., ISO, UN Model Regulations, NFPA, and etc.).

When referring to specific regional authorities; it is important not to write a publication based on regional regulations, which may not apply to other regions.

When harmonizing a project, each Association may substitute equivalent regional documents for the references used by the Lead Association. For example, if an EIGA lead publication references EIGA Doc 10/09, *Reciprocating Compressors for Oxygen Service*, AIGA may replace that reference with AIGA 048/08, *Reciprocating Compressors for Oxygen Service*, in their regional harmonized version.

## **5.2 Mandatory language for harmonized publications**

The following text shall be included in harmonized publications when indicated as a requirement.

### **5.2.1 Regulatory requirements**

The following language shall be inserted following the title page (i.e., on a “Please Note” page or where other information is presented prior to the table of contents) in all harmonized publications to indicate that regional regulations shall be followed when they are more prescriptive than the requirements in the harmonized publication:

*The user is cautioned that regulatory requirements can vary from those presented in this publication. Where conflicts exist, the more prescriptive or stringent requirements shall be followed.*

### **5.2.2 Translation notice**

In any harmonized publications translated from English into another language, the following text shall be inserted following the title page (i.e., on a “Please Note” page or where other information is presented prior to the table of contents) to indicate that the original English publication should be referred to in case of errors of translation:

*Any ambiguities or interpretive differences between an authorized translated version and the original version of this harmonized publication shall be construed and applied to preserve the meaning set forth in the official harmonized version which is available from [insert Association].*

### **5.2.3 Copyrights**

Lead Associations retain the copyright for their publications.

Other Associations shall obtain formal approval from the Lead Association before publication of their regionalized version of the harmonized publication.

The copyright language of the Lead Association shall be included in the regionalized version if required by the Lead Association as noted in the section below.

#### **5.2.3.1 AIGA copyright language**

© – *Reproduced with permission from the Asia Industrial Gases Association. All rights reserved.*

#### **5.2.3.2 CGA copyright language**

*Reproduced with permission from the Compressed Gas Association. All rights reserved.*

#### **5.2.3.3 EIGA copyright language**

© – *Reproduced with permission from the European Industrial Gases Association. All rights reserved.*

#### **5.2.3.4 JIMGA copyright language**

Two statements should appear on harmonized editions of JIMGA lead publications:

*JIMGA reserves the copyright of this document. JIMGA permission is necessary for the copying of this document.*

© – *Reproduced with permission from the Japan Industrial and Medical Gases Association. All rights reserved.*

## 6 IHC meeting materials

The IHC Administrator is responsible for the preparation and distribution of all meeting materials as described below.

### 6.1 IHC meeting agenda

The IHC meeting agenda is prepared using the template provided in Annex E. The agenda should be circulated no less than 30 days prior to the next scheduled IHC meeting. Associations may request to add items to the agenda for discussion prior to the meeting.

### 6.2 IHC project report

The IHC Project Report (IHC PR) is a summary list of all future, active, and closed IHC projects. The report provides concise information regarding the status and proposed or actual completion dates of harmonization projects. Excerpts from the IHC PR are provided throughout the following sections.

#### 6.2.1 Active and Revision Projects

The following sections, as shown in Figure 2, are used in the IHC PR to describe active and revision projects:

- Project No/Lead: The project type identifier (A for Active or R for Revision), unique project number (i.e., 1072), year project initiated (i.e., 2006), and Lead Association (A for AIGA, C for CGA, E for EIGA, J for JIMGA).
- Project Title and Status: Title and status updates from each participating Association since the last issue of the IHC PR.
- Initial Proposed Completion Date: The original date that an individual Association proposes to publish the harmonized publication.
- Revised Proposed Completion Date: The revised date(s) that an individual Association proposes to publish the harmonized publication.

NOTE—Changes to the Revised Proposed Completion Date are recorded in the IHC PR in order to maintain documentation of the adjustment of a project completion date over time.

- Published by the Lead Association: Date that the Lead Association publishes the publication.
- Actual Association Completion Date: Date that individual Associations publish the publication.

IHC Active Projects – Projects which require resources from one or more associations.					
Project No/Lead	Project Title and Status	Initial Proposed completion date	Revised proposed completion date	Published by the lead association	Actual associations publication date
A-1072-2006-E	<u>Safe location of oxygen and nitrogen vents</u> AIGA –Has been published. CGA –See EIGA comments EIGA – Following a number points raised by CGA, document will be further reviewed with CGA on how to resolve. JIMGA – Work has started to review the Japanese version.	A-2Q/2010 C-3Q/2010 E-1Q/2009 J-4Q/2010	C-4Q/2010 C-1Q/2011 C-4Q/2011 J-4Q/2011	E-1Q/2009	A-2Q/2010 E-1Q/2009

Figure 2—IHC Project Report, Active and Revision Projects

#### 6.2.2 Closed Projects

The following sections, as shown in Figure 3, are used in the IHC PR to describe closed projects:

- Project No/Lead: The project type identifier (A for Active or R for Revision), unique project number (i.e., 1072), year project initiated (i.e., 2006), and Lead Association (A for AIGA, C for CGA, E for EIGA, J for JIMGA).

- Project Title: Title of the project.
- Close Date: Date (listed by either year or quarter/year) that all participating Associations completed work and the IHC agreed to close the project.

IHC Closed Projects – Harmonized publication has been published by all participating organizations.		
Project No/Lead	Project Title	Close date
A-1004-0000-E	Safe operation of main condensers in air separation units	2000
A-1012-1999-E	Toxicity of nonmetallics in breathing gas systems	2Q/2009
A-1013-1999-E	Fuel/oxidizer incidents	2001

**Figure 3—IHC Project Report, Closed Projects**

### 6.2.3 Future Projects

The following sections, as shown in Figure 4, are used in the IHC PR to describe future projects:

- Project Title: Proposed title of the project.
- Association Proposed: Identifies the Association (A for AIGA, C for CGA, E for EIGA, J for JIMGA) that submitted the topic to the IHC for consideration as a harmonized publication.
- Date Proposed: The date that the project was initially received by the IHC; this is generally the meeting date that the topic was discussed.
- Existing or New Pub: Identifies whether the proposal is to harmonize an existing publication from an Association's library or to develop a publication on a new topic.
- WIR Scores: The scores of high, medium, or low (H, M, L) given to each proposed topic in the categories of urgency of issue, potential risk/risk involved, and impact or potential impact in the WIR submitted to the IHC for consideration (see Annex A for WIR).
- Risk Scores: The scores of 0, 1, 2, or 3 given to each proposed topic in the categories of probability, severity, impact during the IHC review of the WIR (see Sections 4.4, 4.5, 4.6, and Annex B for information on the prioritization of projects).
- IHC Decision: A record of the IHC decision to approve as an active or revision project, add to the list of future harmonization projects, or disapprove the project proposal.

IHC Future Projects – Topics that have been proposed but not assigned an IHC project number.						
Project Title	Association Proposed	Date Proposed	Existing or New Pub	WIR Scores (Urgency/Risk/Impact)	Risk Scores (Probability/Severity/Impact)	IHC Decision
Cleaning Equipment for Oxygen Service (CGA G-4.1)	C	Jan 2011	Existing	M/M/M	1/3/0	Disapproved
Fire in LOX Vacuum Jacketed Piping (EIGA Safety Information 23/10)	C	Jan 2011	Existing	M/M/H	3/3/3	Active Project
LOX, LIN, and LAR Cryogenic Tanker Loading System Guide (CGA P-31)	E	Jan 2011	Existing	M/H/M	3/2/3	Active Project
<b>PROPOSED TOPICS NOT YET EVALUATED:</b>						
Access and Activity Restrictions	E					
Acetylene (CGA G-1)	C		Existing			

**Figure 4—IHC Project Report, Future Projects**

### 6.3 IHC meeting minutes

Minutes shall be recorded at each IHC meeting. The draft minutes shall be distributed to all Association Technical Liaisons for review no later than 4 weeks after the meeting.

At the next IHC meeting, the minutes shall be approved and marked as final. The final minutes shall be distributed to all Association Technical Liaisons.



## 7 IOMA Global Committee reports

The CGA and EIGA IHC Association Representatives are alternately responsible for preparing and presenting a report on harmonization for the IOMA Global Committee meeting. The report shall include information regarding:

- Work process issues;
- Review of active “A” projects, by exception;
- Review of active “R” projects, by exception;
- Project Summary Table (e.g. Table 1);
- Proposed new projects (WIRs);
- Hydrogen regulatory activities impact report (on a semi-annual basis);
- UN/ISO activities impact report (only when IHC Associations’ positions differ on these issues); and
- IOMA Global Committee Harmonization Award (for the Spring IOMA Meeting only, see Annex D).

**Table 1—Example of IHC Project Summary Table**

		Published By Associations					
Project Type	Draft in Preparation	1st	2nd	3rd	Total WIP	Closed	Total
New Projects	16	5	4	5	30	23	
Revisions	7	0	3	1	11	3	
Totals	23	5	7	6	41	26	67

## Annex A—IHC Work Item Request (WIR)

**Proposed by: [Association]  
At IHC Meeting [meeting number] in [city] on [day month year]**

**Title:**

Maximum 7 words.

**Project Type:**

- ☐ New harmonization project
- ☐ Draft of new document – no existing Association publications
- ☐ Harmonization of existing Association publication
- ☐ Revision of existing harmonization project (Original IHC Project Number: )
- ☐ Lead Association recommends revision of publication
- ☐ Lead Association recommends deferring revision of publication (Proposed revision date: )
- ☐ Lead Association recommends reaffirmation of publication

**Introduction**

Origin and description of subject, issue or problem.

**Purpose**

Justification, clear objective(s), benefit to members.

**Scope**

What is included and what is not included.

**Existing Publications**

List all related publications (e.g., Association, ISO, CEN, I-Code, NFPA, and other related publications developed outside of the industrial gas industry) and reasons for not adopting.

**Resources**

Required man-days to be spent in joint meetings and homework; additional expected costs.

**Critical Success Factors**

List all factors that could delay publication.

**Project Assignment Criteria**

Each potential harmonization project shall be evaluated against the following criteria:

**Urgency of Issue**

- History / precedent / notable incidents
- Legislative / regulatory / legal attention
- Availability and adequacy of existing guidance

**Rating**

☐ High

☐ Medium

☐ Low

**Potential Risk/Risk involved**

- Product quality / acceptability
- Risk of fatality / injury to employees
- Risk of fatality / injury to contractors / third parties
- Risk of fatality / injury to public
- Environmental impact / regulation

**Rating**      ☐ High      ☐ Medium      ☐ Low

#### **Impact or Potential Impact on the Industry**

- Positive or negative image - regulators / public / media
- Cost implications – operational change / business
- Significance to the business

**Rating**      ☐ High      ☐ Medium      ☐ Low

#### **Recommended Work Process**

Propose and justify the choice of a Lead Association and work process (full joint working group, partial joint working group, or lead association publication).

- ☐ **Full Joint Working Group** (JWG develops or submits comments to revise existing publication, Lead Association circulates publication for comment, and JWG resolves comments from all Associations)
- ☐ **Partial Joint Working Group** (Lead Association circulates draft or existing publication for comment, comments resolved by JWG)
- ☐ **Lead Association Publication** (Lead Association circulates draft or existing publication for comment and resolves comments as they are received from each participating Association)

#### **Justification for recommended work process:**

#### **Expected Completion Date**

List by Association the expected publication quarter for incorporation in the timeline reports.

	Lead Association (Mark with "x")	Association Supports Project? (Y or N)	Association Participates in Project? (Y or N)	Proposed Completion Date	Contact
AIGA					
CGA					
EIGA					
JIMGA					

#### **Other milestones:**

e.g. comments close date, draft preparation schedule

## **Annex B—IHC Prioritization of Proposed Harmonization Projects**

Using the information provided in the WIR (see Annex A) and Tables B1 and B2, proposed harmonization projects are evaluated for acceptance.

Projects which score high in the industry impact, probability, and severity ratings will be automatically accepted into the active projects list. Projects with a moderate score in the industry impact, probability, and severity will be placed in the future projects queue. Projects which receive a score of “low” in all three categories will be assigned a lower priority. See section 4.6 for process of harmonization project acceptance.

A risk based assessment is used to score future projects (see Table B1).

A WIR is required for revision projects. When revision comments are received from all participating Associations, the Lead Association makes a recommendation to revise the publication, delay revision for up to 7 years after the Lead Association’s publication date, or reaffirm the publication (see section 4.1.5 for information).

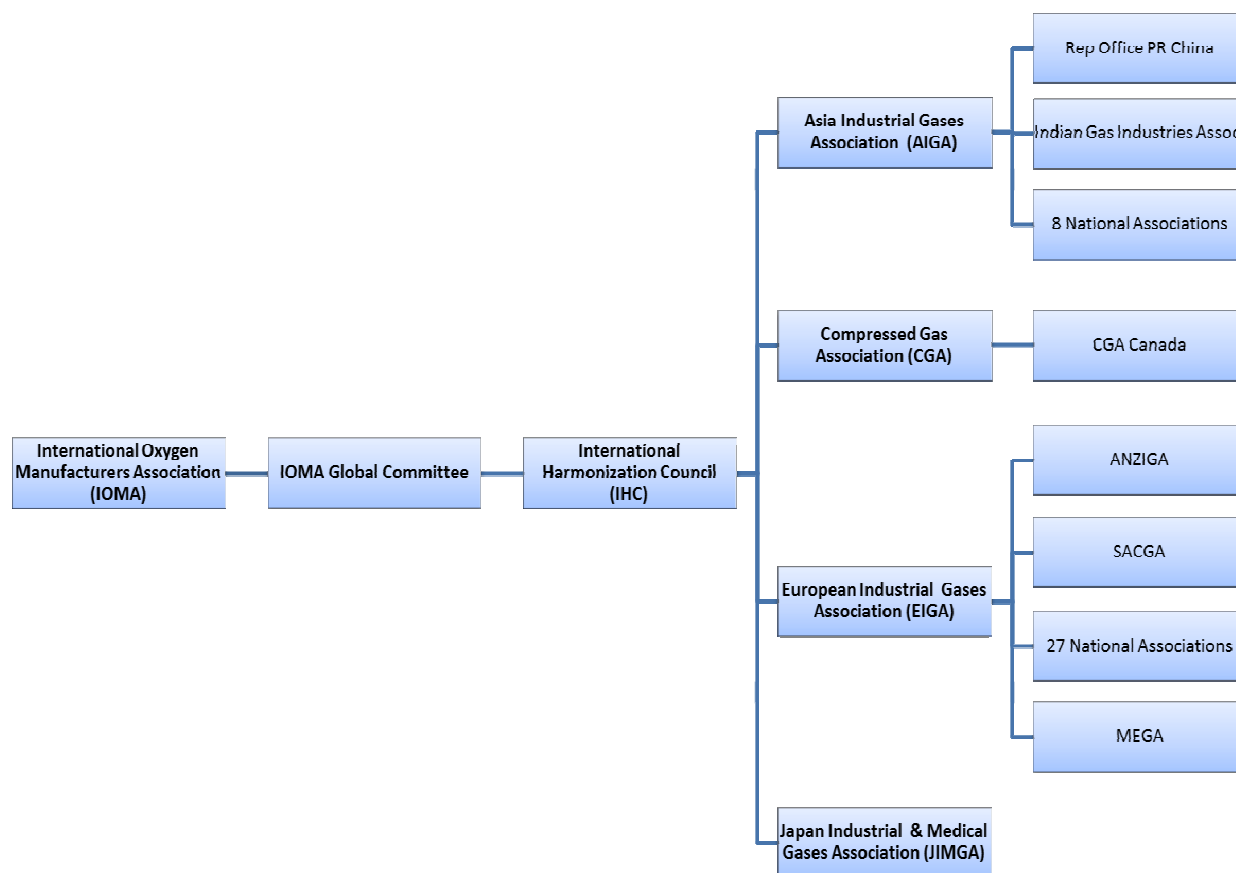
All accepted proposed future and revision projects will be prioritized based on their safety risk score, which is obtained by using the calculation below. High scoring projects receive a priority for work and resources.

(Probability x Severity) + (Impact on Industry x Impact on Standards) = Safety Risk Score

**Table B-1—IHC Scoring Criteria**

Safety		Impact	
<u>PROBABILITY</u> If this project is not accepted, what is the estimated probability of the issue occurring over 5 years?	<u>SEVERITY</u> If this project is not accepted, what is the estimated severity if the issue occurred?	<u>IMPACT ON INDUSTRY</u> If this project is not accepted, how much of the international gases industry will be impacted?	<u>IMPACT ON STANDARDS</u> If this project is not accepted, what is the impact on industry standards?
<input type="checkbox"/> 4 – High (very likely, possibility of repeated incidents)	<input type="checkbox"/> 4 – Fatality to personnel or serious impact on public	<input type="checkbox"/> 4 – Most of the industry impacted	<input type="checkbox"/> 4 – Associations have publications on this topic with conflicting or different requirements, or do not have positions on this topic
<input type="checkbox"/> 3 – Medium (somewhat likely, possibility of isolated incidents)	<input type="checkbox"/> 3 – Serious injury to personnel or limited impact on public	<input type="checkbox"/> 3 – Some of the industry impacted	<input type="checkbox"/> 3 – Topic is addressed by outside publications not formulated with industry specific guidance
<input type="checkbox"/> 2 – Low (unlikely, possibility of occurring sometime)	<input type="checkbox"/> 2 – Medical treatment for personnel or no impact on public	<input type="checkbox"/> 2 – Small or regional sector of the industry impacted	<input type="checkbox"/> 2 – Topic is addressed by outside publications formulated with industry specific guidance or by regulation
<input type="checkbox"/> 1 – Very unlikely, practically impossible	<input type="checkbox"/> 1 – Minor impact on personnel	<input type="checkbox"/> 1 – Unlikely to impact the industry	<input type="checkbox"/> 1 – Association publications address the issue without difference or conflict and/or are harmonized
To aid in the review of this proposed work item you may wish to explain the rational for your ratings:			
_____	_____	_____	_____

## Annex C—Organization Structure of IOMA and IHC Associations



## **Annex D—IOMA International Harmonization Award Criteria**

The award, sponsored by the IOMA Global Committee, is for significant and distinguished service to the International Harmonization Process and is presented to an individual who best exemplifies the character, commitment, and technical excellence prevalent in the development of harmonized publications or legislation at the international level.

*Eligibility:* Any employee of an IHC member company or associate organization, including both working and retired employees. Full time IHC Association staff members are not eligible for this award. Previous winners shall wait five years before being eligible again for nomination for the award.

*Nomination Process:* Only one candidate may be proposed by each IHC Association and the details of the candidate should be submitted to the spring meeting of the International Harmonization Committee, (IHC).

At the IHC spring meeting, the suitability of the nominated candidates against the criteria for the award shall be discussed. The details of the selected candidates shall be forwarded to the IOMA Global Committee immediately after the IHC spring meeting.

The IOMA GC requires at least two candidates to be presented for consideration each year. If a particular candidate is not selected, the IHC Association may carry their nomination forward to subsequent years indefinitely, or may nominate a new candidate in the subsequent years.

*Judging:* The award winner shall be decided at the spring meeting of the IOMA Global Committee. The Executive Director of IOMA shall inform the winning candidate.

*Criteria:* The award shall be based solely on:

- The individual's record of achievement and leadership on behalf of the industry;
- The individual's reputation and professional recognition in the industry;
- The individual's reputation and recognition by international and national authorities; and
- The individual's involvement and cooperation with the industry and the authorities in developing and promoting harmonized legislation and standards.

*Presented:* At the Annual Meeting of IOMA held in the fall.

**Annex E—IHC Meeting Agenda Templates**

**PRE-MEETING [DRAFT] AGENDA**

**INTERNATIONAL HARMONIZATION COUNCIL**  
**Pre-Meeting for No. [xx]**  
**[date]**  
**Webconference**

[day] – [time]

1.	<b>Welcome and administrative matters</b> a. Circulate sign in sheet b. Antitrust reminder c. Introductions	[xx]
2.	<b>Approval of agenda</b>	All
3.	<b>Discussion topics</b> a. [Topics that require discussion/work prior to next IHC meeting]	All
4.	<b>Any other business</b>	
5.	<b>Closing Remarks</b>	All
6.	<b>Next Pre-Meeting for No. [xx]</b> a. Proposed Date: To be determined at Meeting No. [xx] in [location] b. Webconference	All
7.	<b>Adjournment</b>	



**[DRAFT] AGENDA****INTERNATIONAL HARMONIZATION COUNCIL****Meeting No. [xx]****[date]****[venue name]****[city, country]**

[day] – [time] – [meeting room]

1.	<b>Welcome and administrative matters</b> a. Circulate sign in sheet b. Antitrust reminder c. Introductions	[meeting chair]
2.	<b>Approval of agenda</b>	All
3.	<b>Review and approval of minutes of Meeting No. [xx] held in [location]</b>	All
4.	<b>IOMA Global Committee</b> a. Report from the [date] Meeting b. Discuss IOMA GC requests	MT/PB
5.	<b>Liaison Reports</b> a. AIGA b. CGA c. EIGA i. ANZIGA ii. SACGA d. JIMGA	LWK RC AW  HM
6.	<b>Review of the IHC Work Process</b>	All
7.	<b>Review of Active Projects</b> See IHC PR for list of projects.	All
8.	<b>Review of Revision Projects</b> See IHC PR for list of projects.	All
9.	<b>Review and Prioritization of Future Projects</b> See IHC PR for list of projects.	All
10.	<b>Review of Closed Projects</b> Confirm closed project(s) a. [list projects]	All

11.	<b>Review of proposed projects for IHC Meeting No. [xx]</b> a. New WIRs <u>AIGA</u> -[list WIRs] <u>CGA</u> -[list WIRs] <u>EIGA</u> -[list WIRs] <u>JIMGA</u> -[list WIRs]	All
12.	<b>IOMA GC “IHC Project Summary Table”</b> a. Prepare table during meeting	All
13.	<b>Development and Review of Future Hydrogen Work</b> a. IHC review of report of hydrogen activities – relevance to harmonization	RC AW All
14.	<b>Review of ISO, UN and other harmonization projects</b> a. United Nations TDG – Monitor activities of the sub-committee on the transport of dangerous goods and identify opportunities or barriers to promote a unified industry position. b. United Nations GHS – Monitor activities of the sub-committee on classification and labeling of chemicals and identify opportunities or barriers to promote a unified industry position c. ISO Technical Committees and Subcommittees – Monitor activities and work towards a harmonized position on issues of importance to the industrial gas industry, particularly TC 58 (SC 2, SC 3, SC 4), TC 197 and TC 220. Identify potential barriers. d. Food Gases - Share information and comments on food gases to include carbon dioxide, nitrogen, argon, oxygen and helium	All
15.	<b>Medical Gases Activities</b> a. Medical gases liaisons b. Joint medical gases meetings	All
16.	<b>Safety and Security Activities</b> a. Security updates b. Safety updates c. Reports on former IHC projects: <ul style="list-style-type: none"> <li>– A-1097, <i>Site Security</i></li> <li>– A-1098, <i>Transport Security</i></li> <li>– A-1099, <i>Qualifying Customers for Purchasing Compressed Gases</i></li> </ul>	All
17.	<b>Any other business (AOB)</b> a. Joint seminars/meetings b. Other items	All
18.	<b>Closing Remarks</b>	All

---

19.	<b>Next Meetings</b> <u>Meeting No. [xx] – Hosted by [Host Association]</u> a. Date: [date] b. Location: [location] c. Pre-meeting Teleconference Date: [date] <u>Meeting No. [xx] – Hosted by [Host Association]</u> a. Date: [date] b. Location: [date]	[xx]      [xx]
20.	<b>Adjournment</b>	All

## Annex F—Submitting Comments to Publications

NOTE – This system is currently set up for CGA work projects, and is under development to accommodate IHC work projects.

Proposed changes (PCs) are linked to Work Items associated with the revision of a particular edition of a harmonization project.

- PCs can be found by searching for:
  - CGA publication number or CGA work item number; or
  - PC ID number or PC cut-off date.

### Video – New Proposed Change Entry Process

- To view the PC submission process video – click on the link below from the PCL outline page, or [click here](#).
- To Add a PC click the add PC icon (📄) next to the section and paragraph number in the publication outline where you wish to add a PC:

Publication ▶ G-1.7 (edition 4) ▶ 10-019 (Mem-Rev) > Outline



Click here for video introduction to the PC Submission process.

Use this page to select a **specific location** within the publication (*Section + Paragraph*), then **click the Add PC button** to proceed. The PC Cutoff date is 06/05/11.

If you are proposing a new section or paragraph, select the location that it will follow.

Locations with yellow color-coding indicate that one or more PCs have been received.

Click the 📄 button in the **PC Count** column to view the **Mini-PCL** for a selected Section/Paragraph.



Click here for the complete PCL.



### Publication Outline

Select location and click 'Add PC'

Manage ? Help

Add PC	Section	Paragraph	Heading	Format	PC Count	Workspace
📄	Title	1	Standard for Storage and Handling of Calcium Carbide in Containers	Other	0	📄
📄	All	1		Other	0	📄
📄	TBD	1		Other	0	📄
📄	1	1	Introduction	HTML	0	📄
📄	2	Header only	Scope and Purpose	Other	0	📄
📄	2.1	1	Scope	HTML	0	📄
📄	2.2	1	Purpose	HTML	0	📄
📄	3	Header only	General Information	Other	0	📄
📄	3.1	1	Nomenclature	HTML	0	📄
📄	3.2	1	Physical properties	HTML	0	📄

- Select the type of PC you wish to submit:

Publication > G-1.7 (edition 4) > 10-019 (Mem-Rev) > Outline > add new PC



### PC Add

Publication: G-1.7

Section: 1

Paragraph: 1

Text:

This publication is one of a series compiled by the Compressed Gas Association, Inc. to provide information on the production, transportation, handling, and storage of compressed gases, cryogenic liquids, and related products.



Select from the available options:

	Revise, Add or Delete text
	Comment, Question or Editorial change
	Add a new Section or Paragraph
	Help me Choose
	Cancel, return to Outline

All content on this page is subject to CGA's Terms of Use and Privacy Policy

- Enter your comments in the text box under the PC Editor. It is important to underline new text and ~~strikethrough~~ text to be deleted.

Publication > G-1.7 (edition 4) > 10-019 (Mem-Rev) > Outline > PC 17909 > this page



PC Editor 17909

Manage Save Cancel Delete Help

**Location:** 1 - paragraph 1

**Type of change:** Revised text

**Proposed change** Edit (markup) the original source text below. (required)

#### Text Markup

Please follow instructions carefully, click inside the editor to start.

To add text:	To indicate text to be deleted:	To enter annotations:
<ul style="list-style-type: none"> <li>enter the new text</li> <li>highlight the new text</li> <li>click the <u>Underline</u> button</li> </ul>	<ul style="list-style-type: none"> <li>highlight the text to be deleted</li> <li>click the <del>Strikethrough</del> button</li> <li><b>Do not delete any text!</b></li> </ul>	<p>If needed for clarity, use square brackets ([]) to indicate additional instructions or comments. These are not Added or Deleted text, they are instructions to the PC evaluators.</p>

This publication is one of a series compiled by the Compressed Gas Association, Inc. to provide information on the production, transportation, handling, and storage of compressed gases, cryogenic liquids, and related products.

- Enter a technical reason that justifies your recommended change (required), identify the source material for your change (optional), and provide any attachments that further support your change (optional). When you are finished, select the save button to complete your submission.

**Reason for change**

Required, proposed changes without sufficient technical reasons might not be considered.

**Source Material**

Optional, but if your Proposed Change is not original material, please include the source below. Original material is considered to be the submitter's own idea based on or as a result of the submitter's own experience, thought, or research and, to the best of his/her knowledge, is not copied from another source.

**Attachments**

Describe content here. Click button to upload your attachments to CGA.



Click to save:

Save

Intellectual Property Rights assignment:

By submitting this form I agree to give CGA all and full rights, including rights of copyright and I understand that I acquire no rights in any publication of CGA in which this proposed change is used.

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## Annex G—Obstacles to the Harmonization Process

Harmonization projects should be chosen carefully using a “bottom up” process involving the Association committee and working group members. Although “top down” directives are possible and can be expected from time to time, however, subsequent acceptance can be difficult to achieve. The obstacles to harmonization can be greater than expected, jeopardizing the success of the project.

There are many potential barriers to creating internationally harmonized publications. Some of these are summarized below:

- **Complicated work processes:** The harmonization work processes are sequential, with many approval steps. This creates opportunities for publications to be constantly reviewed and reworked by different people, which greatly slows down the process of producing a publication.
- **The people using the harmonization work processes do not fully understand them.** This creates more opportunities for errors, delays, and revision of finished work. For example, company representatives may not get input from their entire organization. At later stages, other members of the company may then raise issues and objections, delaying approval.
- **After the technical agreement is reached, the member organizations customize the publication.** Customization of publications can often result in significant delay between the time the lead Association publishes the publications and when the following organizations publish, or may result in two publications that are no longer properly harmonized leading to problems when the publication is to be revised.
- **Publications may rely excessively on references to local codes or standards.** If publications are customized by referring to codes or standards, rather than by defining clearly the technical content of the concerned subject, the publications cannot be understood without reading the reference or may no longer be properly harmonized if codes or standards change.
- **The Associations have different technical terms.** If the Associations do not have common definitions and warnings, this can create confusion or prevent one Association from adopting another’s publications.
- **The Associations have different Management of Change processes.** Some Associations use formal publications management systems, while other Associations may have less formal processes. Each system has its own strengths and weaknesses, but having multiple processes creates confusion and rework.
- **It is difficult to harmonize two existing publications with similar scope but different approaches.** In some cases, two Associations have existing publications with apparently similar scope, but when attempting to harmonize these, it can be very difficult if the approach or purpose is different. For example, if one is more “performance oriented”, while the other provides a more prescriptive methodology, the harmonized publication will be very different for at least one of the organizations.
- **Human Nature.** Harmonization inevitably requires change, but people instinctively resist change and defend their current position.
- **Member companies are not always fully committed.** Harmonization is hard work, and requires companies to commit to the people, time, and funding to make it happen, and to continue support for the projects.
- **Different cultures and languages.** English is the working language of the harmonization process, and so publications will require time and resource to translate into other languages (or vice versa) to ensure proper understanding. Additionally, different cultures can result in different approaches to the industry and result in different interpretations.
- **Language style.** To ensure understanding by all readers, the style shall be as simple and concise as possible. This is particularly important for those readers whose native language is not English.

## **Annex H—AIGA Work Process**

### **H1 Adoption of an existing AIGA document by IHC Member Associations**

IHC member Associations determine they want to harmonize with an existing AIGA document. Upon acceptance as a harmonization project, AIGA assigns a task force.

The Associations review the document, develop proposed changes, and submit them to the Secretary General of AIGA using the IHC Proposed Change (PC) form.

Upon receipt of all comments, the task force schedules meetings to deliberate on the proposed changes and provide feedback to the Associations via the Secretary General. All proposed changes are to be agreed mutually between AIGA and the other associations.

The task force recommends the changes to the Technical Committee.

The Technical committee decides on the proposed changes. The agreed version is then circulated to the other associations for their follow-up. The final version from the associations with the changes highlighted should be submitted to AIGA for record.

### **H2 New document with AIGA as the Lead Association**

Once IHC determines that AIGA takes the lead on a new document, a task force is formed comprising of members from any participating associations.

The task force develops the draft document within 6-12 month. Meetings of the task force may require travel; otherwise use of tele-conference should be maximized.

The draft is circulated to the participating associations for feedback. When the feedback is completed, the approved draft is circulated to the other IHC Associations for comments (participation is welcomed during task force draft development).

The Proposed Change (PC) system is used to gather PCs from other associations and these comments are reviewed. A time frame for feedback is to be agreed with the associations in relation to their internal processes to obtain the feedback.

The task force studies and achieves a consensus with the associations on the amendments required. The draft undergoes a final revision.

The task force submits the final version to the Technical Committee and subsequently to the Board and once they approve it, it is published.

The final version is concurrently sent to the other Associations for their publication. The other associations publish according to their own schedules.

### **H3 AIGA process for adopting document with another IHC Association as the Lead**

AIGA decides if it wishes to be a participating member. If yes, a liaison person from the Working Group is nominated on the project as the AIGA representative. The representative participates in the work of the Lead Association according to the program set. He updates the Working Group or Technical Committee on the project to ensure that AIGA's position is taken care of.

If not, AIGA remains in the 'kept updated' status. When the work is completed by the Lead Association, the final draft is circulated to the designated AIGA Working Group who studies and gives feedback to the Lead Association by the proposed change cutoff date. All proposed changes are to be resolved with the Lead Association.

The agreed revised document is received and sent to the Technical Committee for approval.

The Technical Committee approves the final draft.



**H4 AIGA process for new document when another IHC Association Leads**

For new IHC Association documents in development, AIGA may elect to participate in which case it selects a liaison to participate in the development of the IHC Association document. Although AIGA may not be an active contributor, the AIGA position is given. The liaison keeps the Working Group and Technical Committee updated on the progress of work.

All proposed changes are to be resolved with the lead association.

If AIGA does not elect to participate, it remains in the 'kept updated' status.

When the work is completed by the Lead Association, the final draft is circulated to the Technical Committee for approval.

The Technical Committee approves the final draft.

## Annex I—CGA Work Process

### I1 Adoption of an existing CGA publication by IHC member Associations

1. Approval of an active harmonization project
  - a. A proposed harmonization project is identified by a CGA Committee or another IHC Association.
    - i. The WIR is submitted to the responsible CGA Committee for approval; the Committee's recommendation is forwarded to CGA Standards Council.
    - ii. The WIR is submitted to CGA Standards Council for approval; if disapproved, the work does not proceed
  - b. CGA announces the first meeting details, including a request for JWG participants from IHC Associations.
  - c. IHC Associations provide names and contact information of JWG participants to CGA.
2. Development of draft publication (new publications only)
  - a. The JWG meets to develop the draft publication.
    - i. Meeting scheduled face-to-face or by webconference based on amount and complexity of work to be done.
    - ii. At least one member from each participating Association should attend the meetings.
3. Review of publication
  - a. CGA circulates a Word copy of an existing publication or draft new publication to other IHC Associations for comment, and announces the proposed change (PC) cutoff date.
  - b. The JWG meets to review the publication and develop PCs, or Associations work independently to develop PCs.
  - c. PCs are submitted to the CGA website prior to the PC cut-off date.
4. Resolution of PCs
  - a. CGA staff works with the JWG chair to schedule a meeting to resolve the PCs.
    - i. Meeting scheduled face-to-face or by webconference based on the number and content of PCs.
    - ii. At least one member from each participating Association should attend the meetings.
  - b. The JWG makes decisions to accept, modify and accept, or reject PCs; CGA staff records decisions and reasons for rejection or modification of PCs to CGA's website.
5. Approval of publication
  - a. CGA staff develops a final draft of the publication, with changes shown using track changes.
  - b. CGA staff requests Standards Council approval of the final draft.
  - c. Upon Standards Council approval, CGA staff performs editorial and technical reviews, and circulates a Word copy of the final draft to the participating Associations for approval.
  - d. IHC Associations prepare a regional version of the publication.

NOTE – Only the differences described in section 2.1 shall be permitted in regional versions of harmonized publications.

  - e. IHC Associations request approval of their regional version from their Councils.
    - i. If the IHC Association Council approves the draft, a request for permission to publish with a Word copy of the final draft with changes shown in tracked changes is submitted to CGA.
    - ii. If any IHC Association Council disapproves the final draft, the disapproving Association shall provide a written explanation of the disapproval to CGA.
    - iii. CGA will schedule a JWG meeting to resolve the disapproval.

- iv. Any changes made as a result of PC disapproval resolution are communicated to all participating IHC Associations and will require approval by CGA Standards Council. If resolution cannot be achieved, CGA will not grant permission to publish as a harmonized document; however, Associations may choose to publish unharmonized versions of the document.
6. Publishing
- a. Following approval by all participating Association Councils, CGA will publish.
  - b. Following permission from CGA staff, participating Associations may publish.

## **I2 CGA process with another IHC Association as the Lead**

1. Approval of an active harmonization project
  - a. A proposed harmonization project is identified by a CGA Committee or another IHC Association.
    - i. The WIR is submitted to the responsible CGA Committee for approval; the Committee's recommendation is forwarded to CGA Standards Council.
    - ii. The WIR is submitted to CGA Standards Council for approval; if disapproved, the work does not proceed.
    - iii. Once a harmonization project is approved by IOMA, a CGA committee is assigned the harmonization project based on subject matter, opens a work item, and assigns participants to a task force.
2. Development of draft publication (new publications only)
  - a. Upon receipt from the Lead Association, CGA circulates meeting information and requests for participants to CGA members.
  - b. CGA staff provides the Lead Association with the names and contact information for all CGA participants.
  - c. CGA participants attend Lead Association meetings to complete draft development.
3. Review of publication
  - a. CGA posts a copy of the Lead Association's publication or draft to the CGA website and announces the PC cutoff date established by the Lead Association to CGA members.
  - b. CGA's task force members participate in the JWG and/or work independently to develop PCs.
  - c. PCs are submitted to the CGA website prior to the PC cut-off date.
4. Resolution of PCs
  - a. CGA submits a list of PCs to the Lead Association for consideration.
  - b. CGA's task force members participate in the JWG meeting to resolve all proposed changes.
    - i. Meeting scheduled face-to-face or by webconference based on the number and content of PCs.
    - ii. At least one member from each participating Association should attend the meetings.
  - c. The JWG makes decisions to accept, modify and accept, or reject PCs; CGA staff records decisions and reasons for rejection or modification of PCs to CGA's website.
5. Approval of publication
  - a. Upon receipt of the final draft from the Lead Association, CGA staff prepares a regional version and submits the draft to Standards Council for approval.

NOTE – Only the differences described in section 2.1 shall be permitted in regional versions of harmonized publications.

- i. If CGA Standards Council approves the draft, CGA staff will complete editorial and technical reviews, and submit a request for permission to publish with a Word copy of the final draft with changes shown in tracked changes to the Lead Association.
- ii. If CGA Standards Council disapproves the final draft, a written explanation of the disapproval will be provided to the Lead Association for resolution.

- iii. CGA's task force members will participate in the JWG resolution meeting.
  - iv. Any changes made as a result of PC disapproval resolution will be re-balloted to Standards Council for approval. If resolution cannot be achieved, CGA will not publish the publication as a harmonized document, but may choose to publish a CGA version of the document.
6. Publishing
- a. Upon receipt of permission to publish from the Lead Association, CGA will publish.

## Annex J—EIGA Work Process

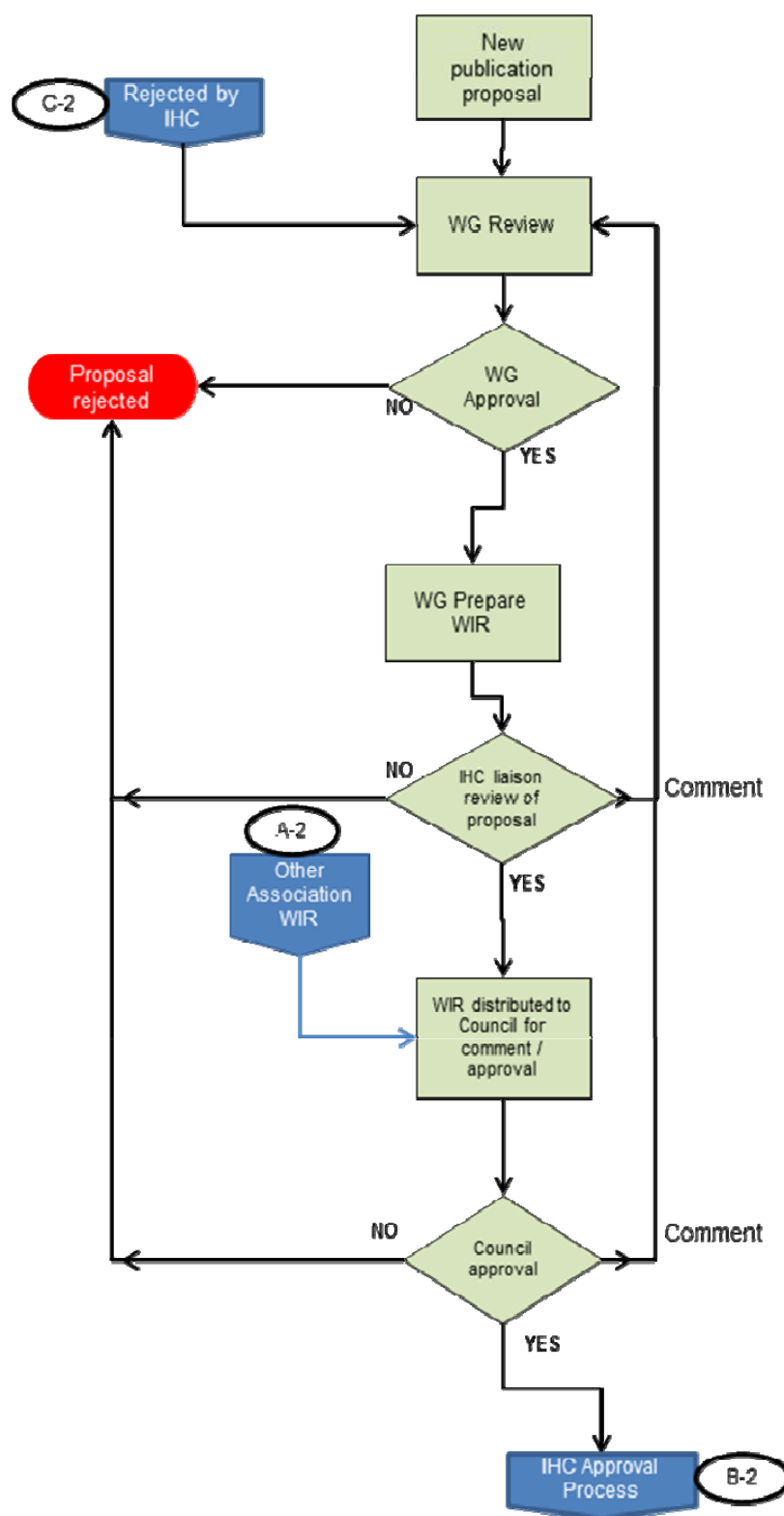


Fig 1 of 6: EIGA New IHC Project Approval

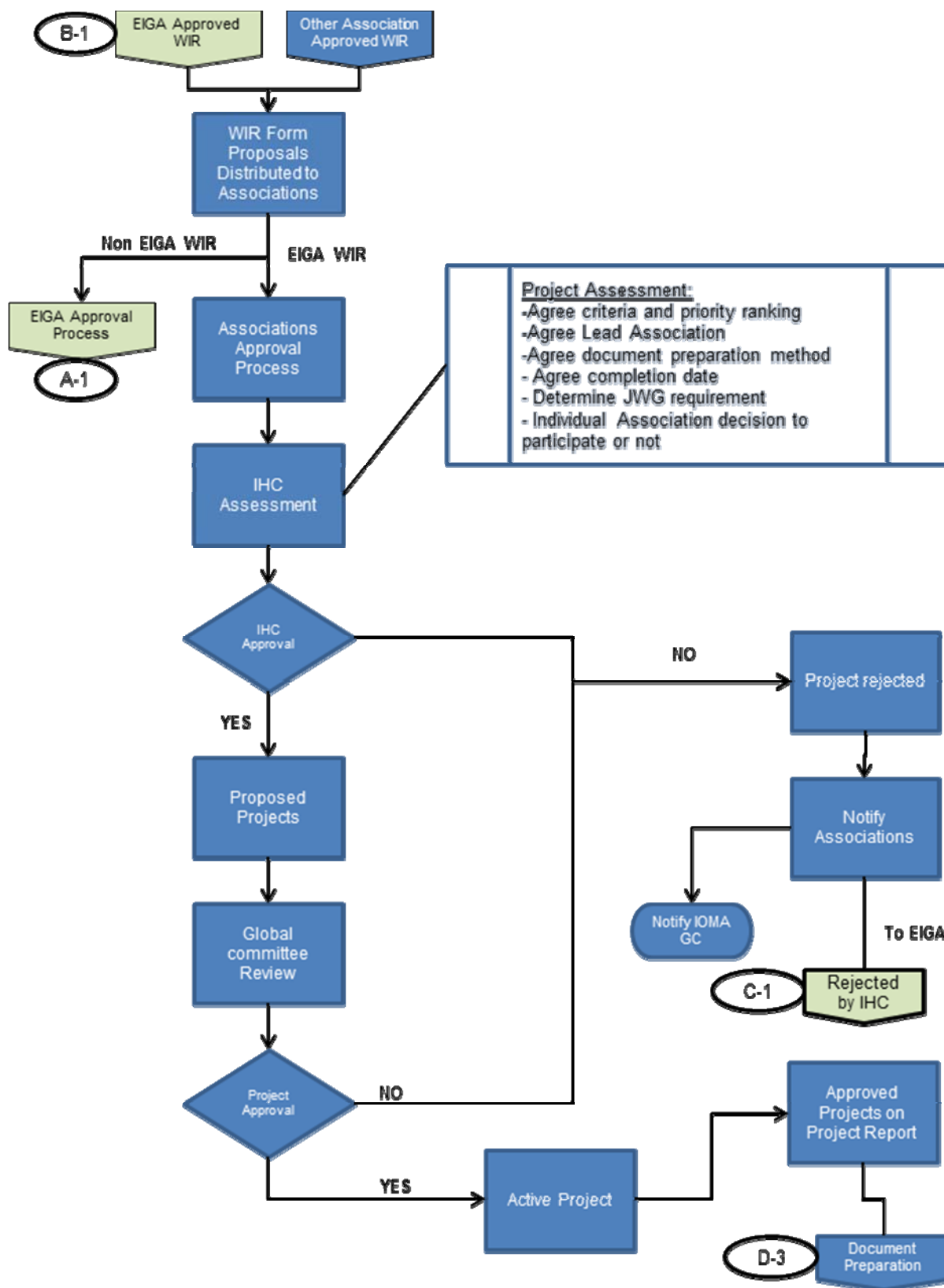


Fig 2 of 6: IHC/IOMA Approval Process

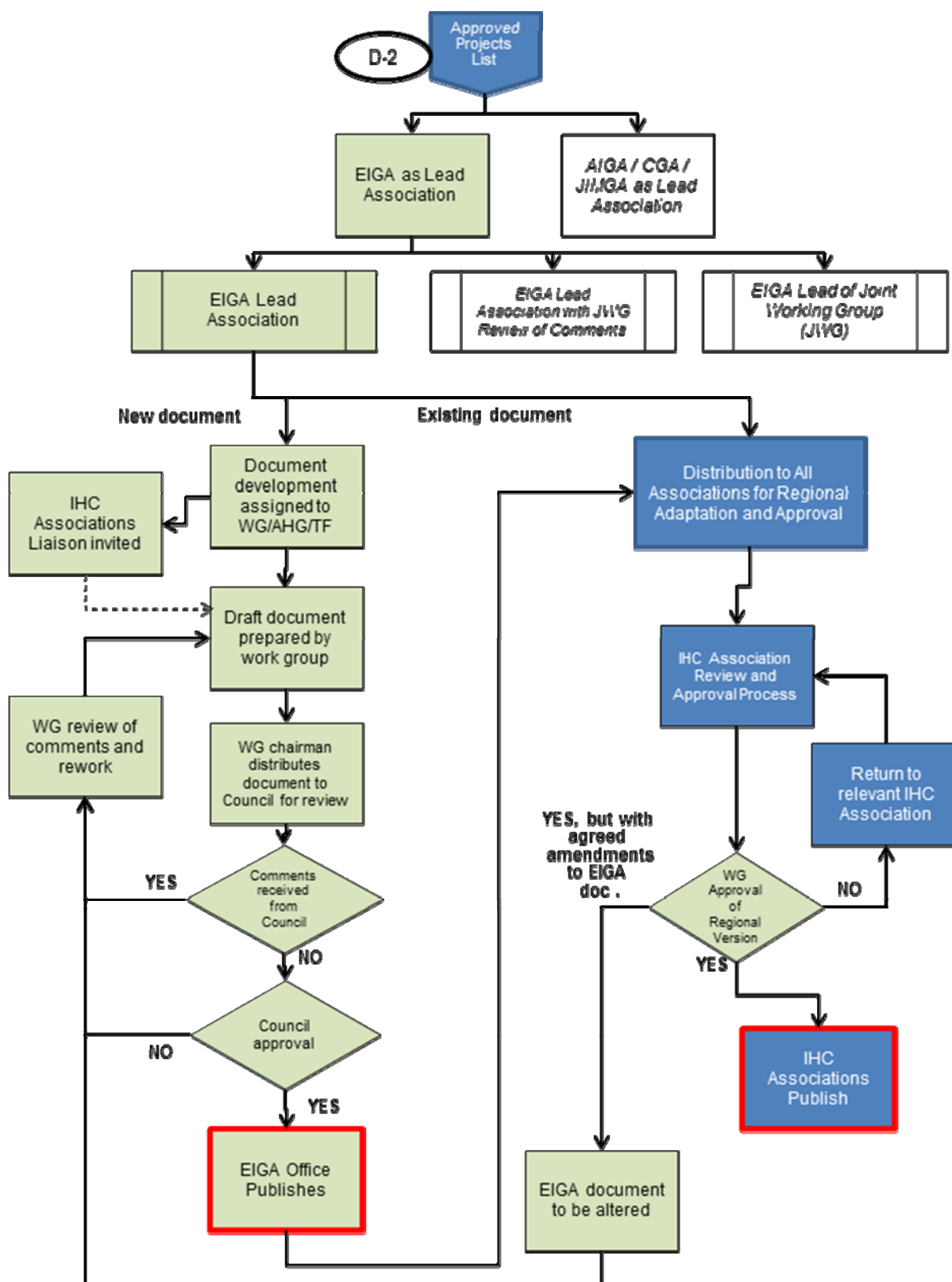


Fig 3 of 6 : EIGA as Lead Association - LA Development

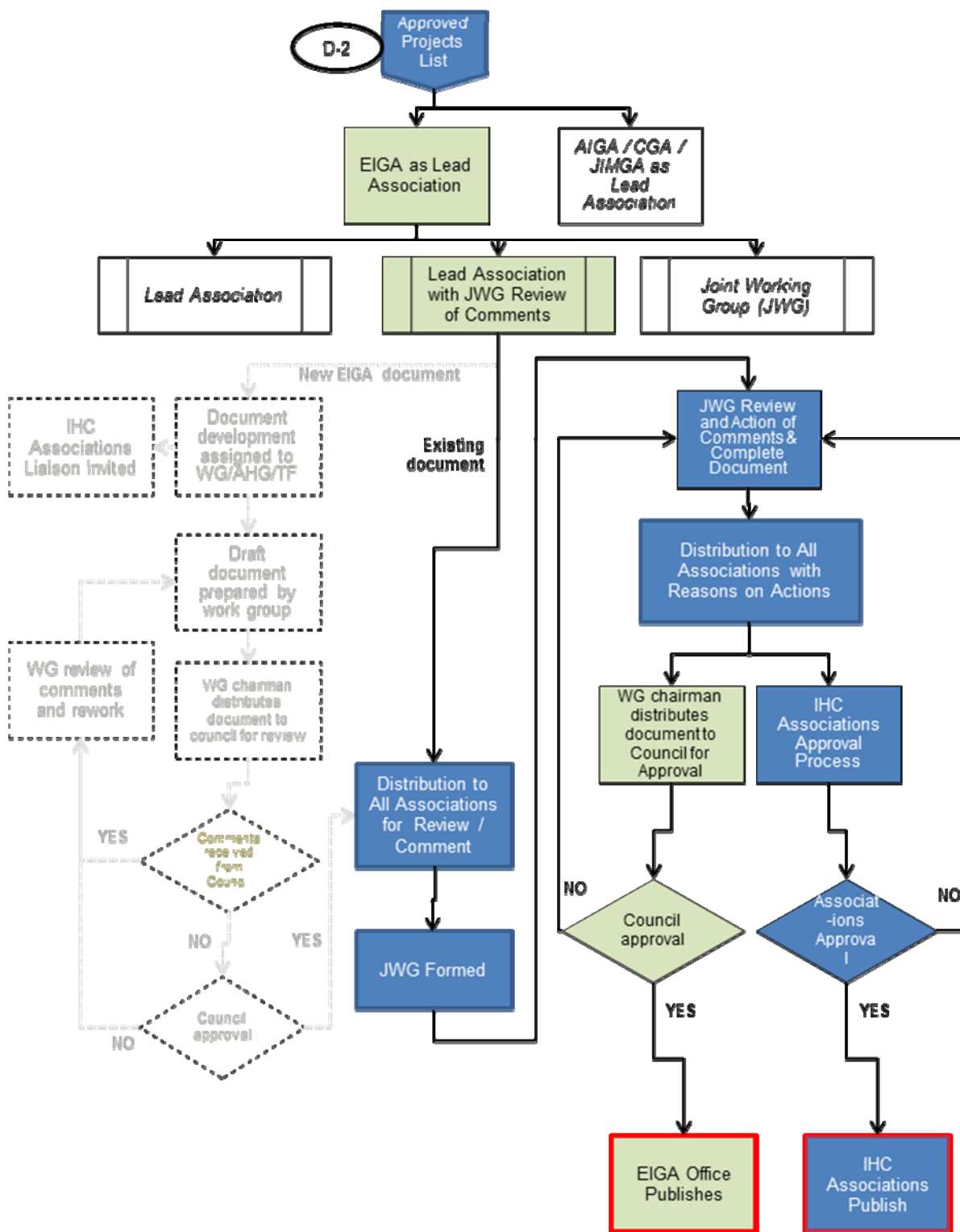
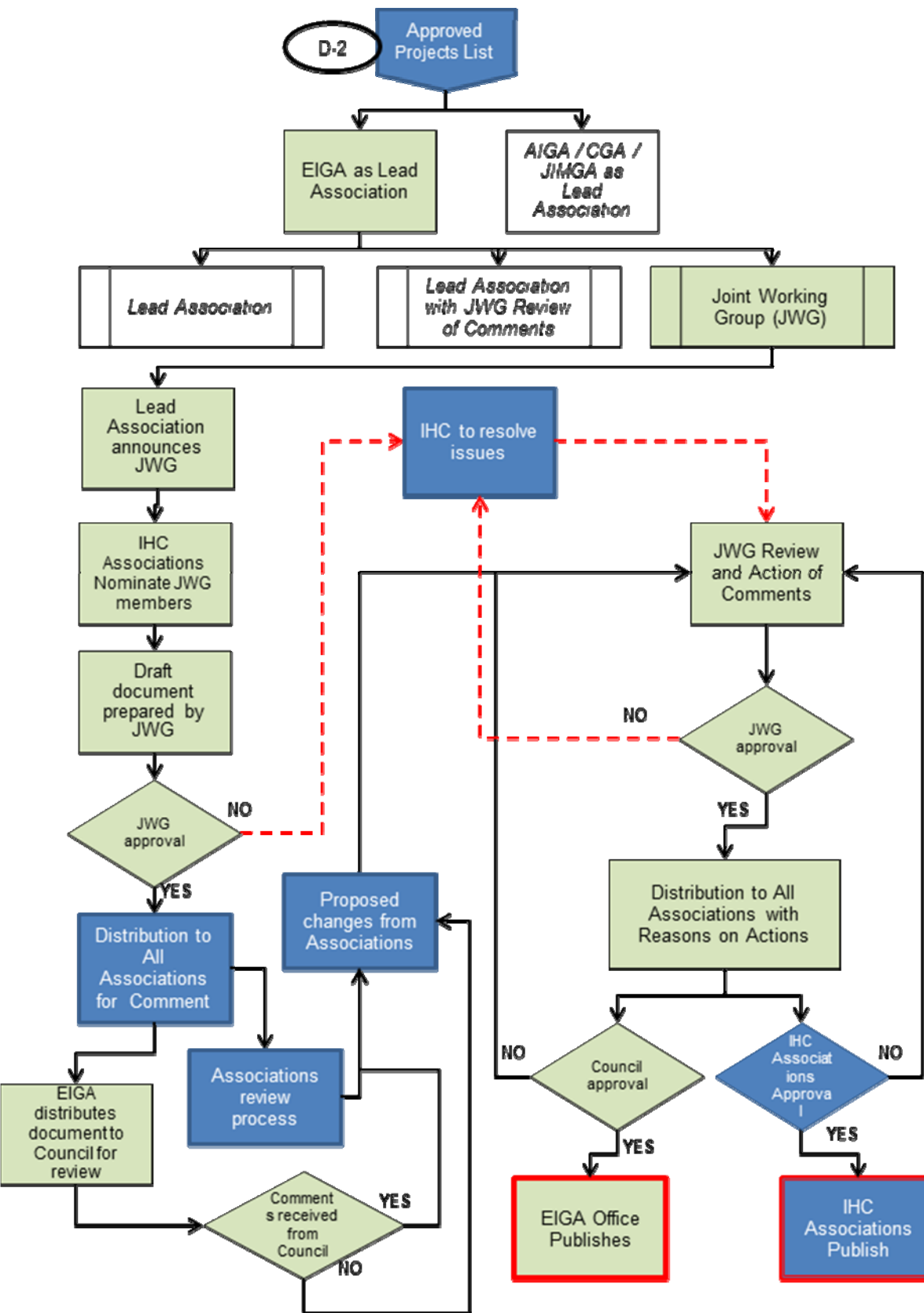
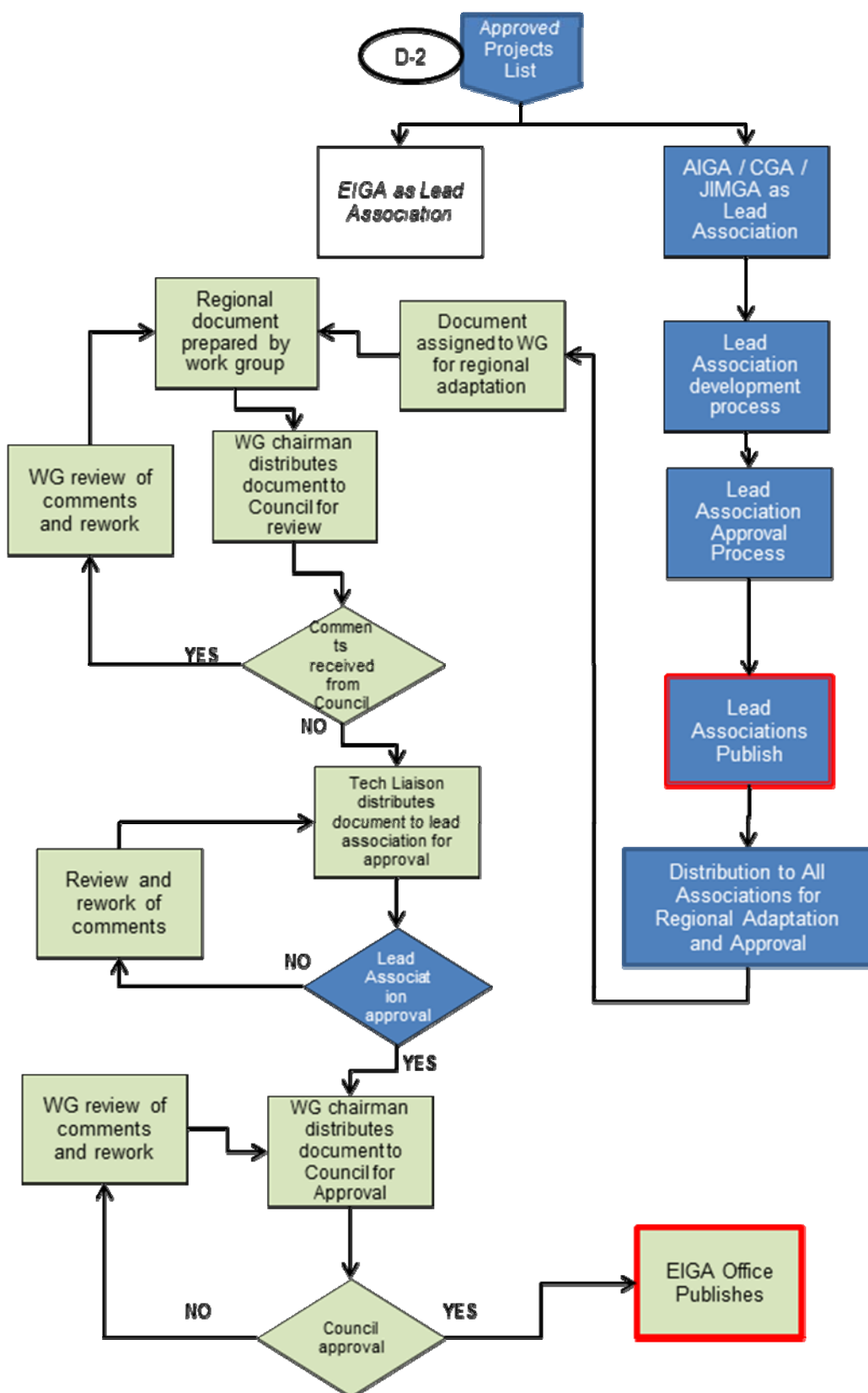


Fig 4 of 6 : EIGA as Lead Association: JWG Review of Comments





**Fig 5 of 6 : EIGA as Lead Association: JWG Development**



**Fig 6 of 6 : EIGA Process for Other as Lead Association**  
**Annex K— JIMGA Work Process**

### Adoption of an Existing JIMGA Document by IHC Association

IHC member Associations determine they want to harmonize with an existing JIMGA document which JIMGA prepared the draft English version. Upon acceptance as a harmonization project, JIMGA will assign a task force on this and prepare the complete English version of the document distributing it to the member associations.

The associations review the document, develop proposed changes and submit them to JIMGA based on the IHC Proposed Changes (PC) form.

Upon receipt of all comments, the task force will schedule meetings to deliberate on the proposed changes and feedback to the Associations. All proposed changes are to be agreed mutually between JIMGA and the other Associations.

The task force will recommend the changes if any to the IHCWG.

The IHCWG decides on the proposed changes. The agreed version is then circulated to the other Associations for their follow-up. The final version from the Associations with the changes highlighted should be submitted to JIMGA for record.

JIMGA will complete the Japanese version of the document and get the approval of the Executive Technical Committee.

### New Document with JIMGA as the Lead Association

Once IHC determines that JIMGA takes the lead on a new document, a task force is formed comprising also members from any participating Associations.

The task force will develop the draft document within a 6 – 12 month timeframe. Meetings of the task force may require travel; otherwise use of tele-conference should be maximized.

The draft is circulated to the participating Associations for feedback. When the feedback is completed, the approved draft will be circulated to the other Associations for comments (participation is welcomed during task force draft development).

The Proposed Change (PC) system will be used to gather proposed changes from other Associations and these comments are reviewed. A time frame for feedback is to be agreed with Associations in relating to their internal processes to obtain the feedback.

The task force will study and achieve a consensus with the Associations on the amendments required. The draft undergoes a final revision.

The task force will submit the final version to IHCWG and subsequently to the Board and once they approved, it will be published.

The final version is concurrently sent to the other Associations for their publication. The Associations will publish according to their own schedules.

JIMGA will complete the Japanese version of the document and get the approval of the Executive Technical Committee.

### JIMGA Process for Adopting Document with Another IHC Association as the Lead

JIMGA will decide if it wishes to be a participating member. If yes, a liaison person from Working Group and / or designated person is nominated on the project as the JIMGA representative. The representative will participate in the work of the Lead Association according to the program set. He will update the Working Group or Executive Technical Committee on the project to ensure that the JIMGA's position is taken care of.

If not, JIMGA will remain in the "kept updated" status. When the work is completed by the Lead Association, the final draft will be circulated to the designated JIMGA Working Group who will study and give feedback to the Lead Association. All proposed changes are to be resolved with the Lead Association.

The agreed revised document is received and sent to IHCWG for approval.

The IHCWG will approve the final draft.

JIMGA will complete the Japanese version of the document and get the approval of the Executive Technical Committee.

JIMGA Process for New Document when Another IHC Association Lead

For new IHC Association documents in development, JIMGA may elect to participate in which case it will select a liaison to participate in the development of the IHC Association document. Although JIMGA may not be an active contributor, the JIMGA position is given. The liaison will keep the Working Group and Executive Technical Committee updated on the progress of work.

All proposed changes are to be resolved with the lead Association.

If JIMGA does not elect to participate, it will remain in the “kept updated” status.

When the work is completed by the Lead Association, the final draft will be circulated to IHCWG or the Executive Technical Committee for approval.

The IHCWG or Executive Technical Committee will approve the final draft.

JIMGA will complete the Japanese version of the document and get the approval of the Executive Technical Committee.

## Annex L—Joint Working Group Process

During the harmonization project approval process, IHC determines the need for a joint working group (JWG) and identifies a Lead Association. The Lead Association is either the owner of the publication, or the proposer of a new publication. The Lead Association is responsible for appointing the JWG chair and providing administrative support for the JWG.

The JWG chair is responsible for coordinating with the JWG members to determine meeting dates, locations, and schedule. Meetings should alternate between regions. Lead Association determines the location of the first meeting. Whenever possible to reduce travel time and costs, “virtual” meetings may be arranged after the first JWG meeting.

The following tables provide steps to be taken by JWG:

**Table L-1—Harmonized publication to be created by JWG (new or existing publication)**

Step	Description	Target Duration (days)
1	IHC recommends approval of project (JWG)	
2	IOMA GC approves IHC proposed A project	
3	CGA assigns project number and informs IHC Associations	
4	Upon receiving information about formation of JWG from Lead Association, IHC Associations announce formation of JWG to their members as appropriate. At end of 30-90 days, IHC Associations offer volunteers for the JWG. Balance of participation from IHC Associations and member companies should be considered.	30-90
5	JWG chair announces meeting date and location for creation of publication. Draft publication completed (may require multiple meetings) and approved by the joint working group members.	
6	Draft publication circulated to IHC Associations for comment. Proposed changes and technical justifications for change shall be captured using the proposed change system or equivalent method. Proposed changes should indicate whether the comment is an editorial or technical change.	60-120
7	JWG chair announces JWG meeting date and location to decide on proposed changes. (NOTE—Virtual meeting may be sufficient.)	
8	JWG meets to decide on proposed changes. Decisions on proposed changes sent to submitters with reasons. If there is no agreement in the JWG, issues are resolved by the IHC as soon as possible (by teleconference or next meeting, whichever is earlier).	
9	The revised publication showing tracked changes and proposed change list are sent to the IHC Associations for final CGA and EIGA Council or AIGA and JIMGA Technical Committee approval.	30
10	If approved, publication is published by all IHC Associations and project is closed. If not, disapprovals are resolved by the JWG with the goal of achieving full consensus. Technical changes shall be sent back to IHC Associations for action. Editorial proposed changes submitted at the approval body stage can be deferred to the next revision. If no agreement is achieved at the JWG level or between Associations, then the issue is referred to IHC for resolution.	

**Table L-2—Existing harmonized publication to be revised by JWG**

<b>Step</b>	<b>Description</b>	<b>Target Duration</b>
1	Associations recommend to IHC harmonized publications for revision and IHC agrees to JWG	
2	CGA assigns project number and informs IHC Associations	
3	Upon receiving information about formation of JWG from Lead Association, IHC Associations announce formation of JWG to their members as appropriate. At end of 30-90 days, IHC Associations offer volunteers for the JWG. Balance of participation from IHC Associations and member companies should be considered.	30-90
4	Draft publication circulated to IHC Associations for comment. Proposed changes and technical justifications for change shall be captured using the proposed change system or equivalent method. Proposed changes should indicate whether the comment is an editorial or technical change.	60-120
5	JWG chair announces JWG meeting date and location to decide on proposed changes. (Note: Virtual meeting may be sufficient.)	
6	JWG meets to decide on proposed changes. Decisions on proposed changes sent to submitters with reasons. If there is no agreement in the JWG, issues are resolved by the IHC as soon as possible (by teleconference or next meeting, whichever is earlier).	
7	The revised publication showing tracked changes and proposed change list are sent to the IHC Associations for final CGA and EIGA Council or AIGA and JIMGA Technical Committee approval.	30
8	If approved, publication is published by all IHC Associations and project is closed. If not, disapprovals are resolved by the JWG with the goal of achieving full consensus. Technical changes shall be sent back to IHC Associations for action. Editorial proposed changes submitted at the approval body stage can be deferred to the next revision. If no agreement is achieved at the JWG level or between Associations, then the issue is referred to IHC for resolution.	

***Explanatory Notes:***

- a) Translation time will be 90 days.
- b) A participant at a JWG is nominated as a subject matter expert, SME, by their company. An important point of principle is that where a company sends more than one SME, they present a common company view.  
  
The SME is an acknowledged expert in their field and as such should present knowledge on the subject.
- c) A publication is ready for approval by the Associations once the JWG has reached full consensus and agreed that it is complete.

## Annex M—Harmonized Definitions

The following definitions have been harmonized and shall be put into all publications as a standard.

- **Shall** indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.
- **Should** indicates that a procedure is recommended.
- **May** and **Need Not** indicate that the procedure is optional.
- **Will** is used only to indicate the future, not a degree of requirement.
- **Can** indicates a possibility or ability.
- **Publications:** This is the generic term adopted by IHC for the output from the harmonization process. Associations will use their own terminology for publications, e.g. standards, publications, bulletins.

There are existing publications which do not use the definitions exactly. These publications may be approved and harmonized by other Associations. In those cases, the definitions for the above terms shall be stated in the publication, and shall override the general definitions given above. Although redefining harmonized terms within a publication is allowed, it is strongly discouraged. Working groups should strive to use the harmonized definitions in this Annex when working on both new and existing publications.

### – Hazardous Warning Terms

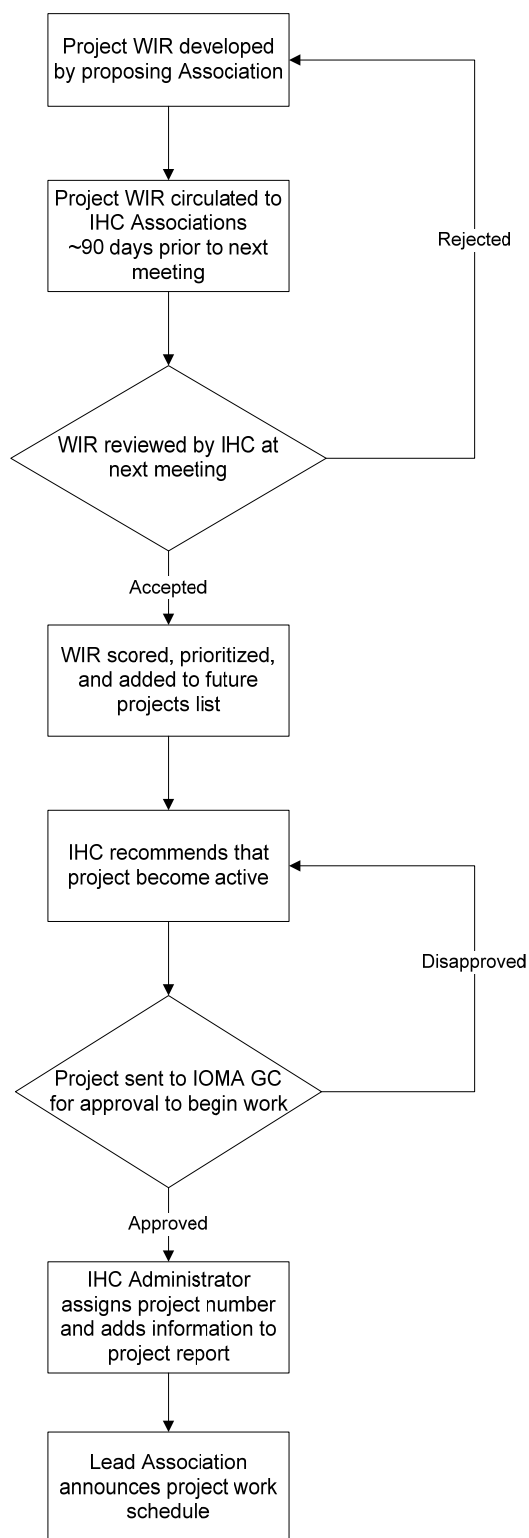
The following definitions apply to the introductory hazardous warning terms:

**DANGER** indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

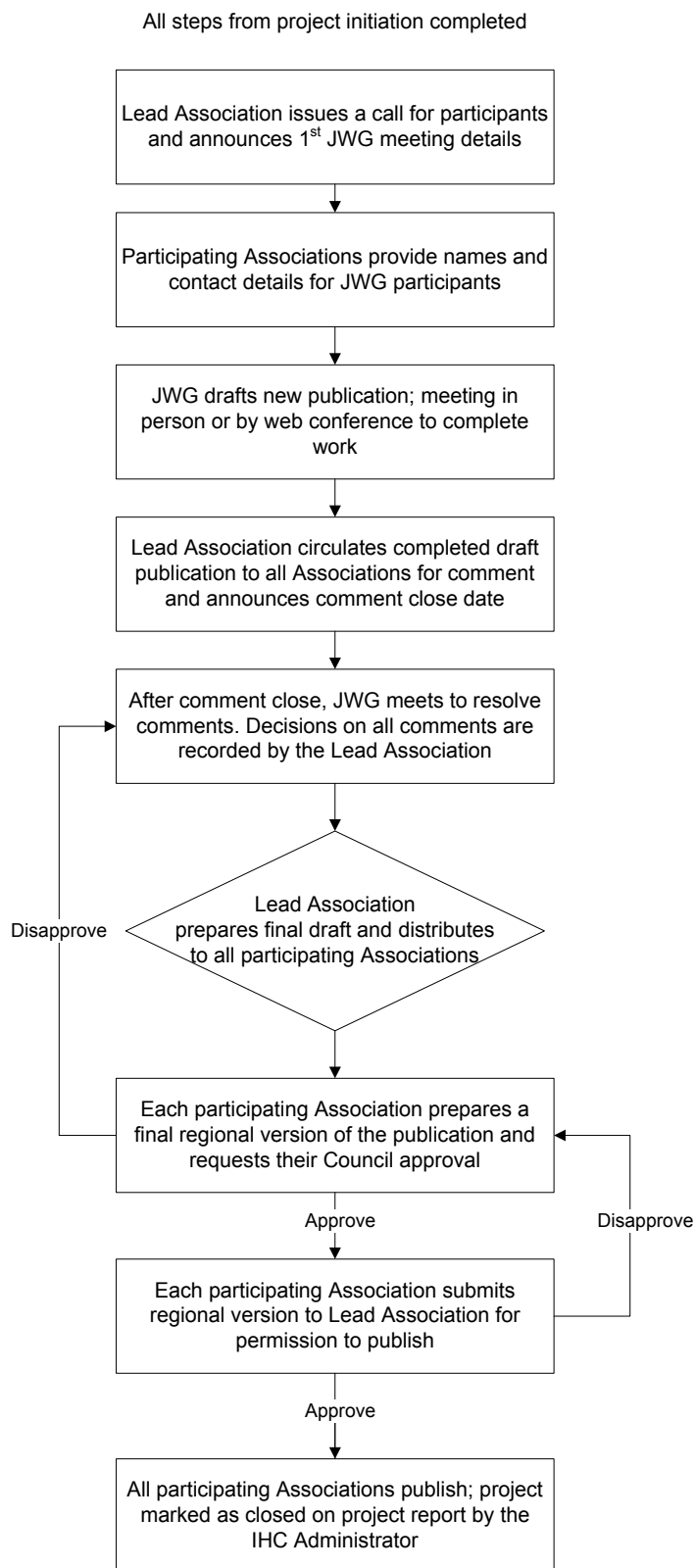
**WARNING** indicates a potentially hazardous situation that, if not avoided, can result in death or serious injury.

**CAUTION** indicates a potentially hazardous situation that, if not avoided, can result in minor or moderate injury. It may also be used to alert against unsafe practices.

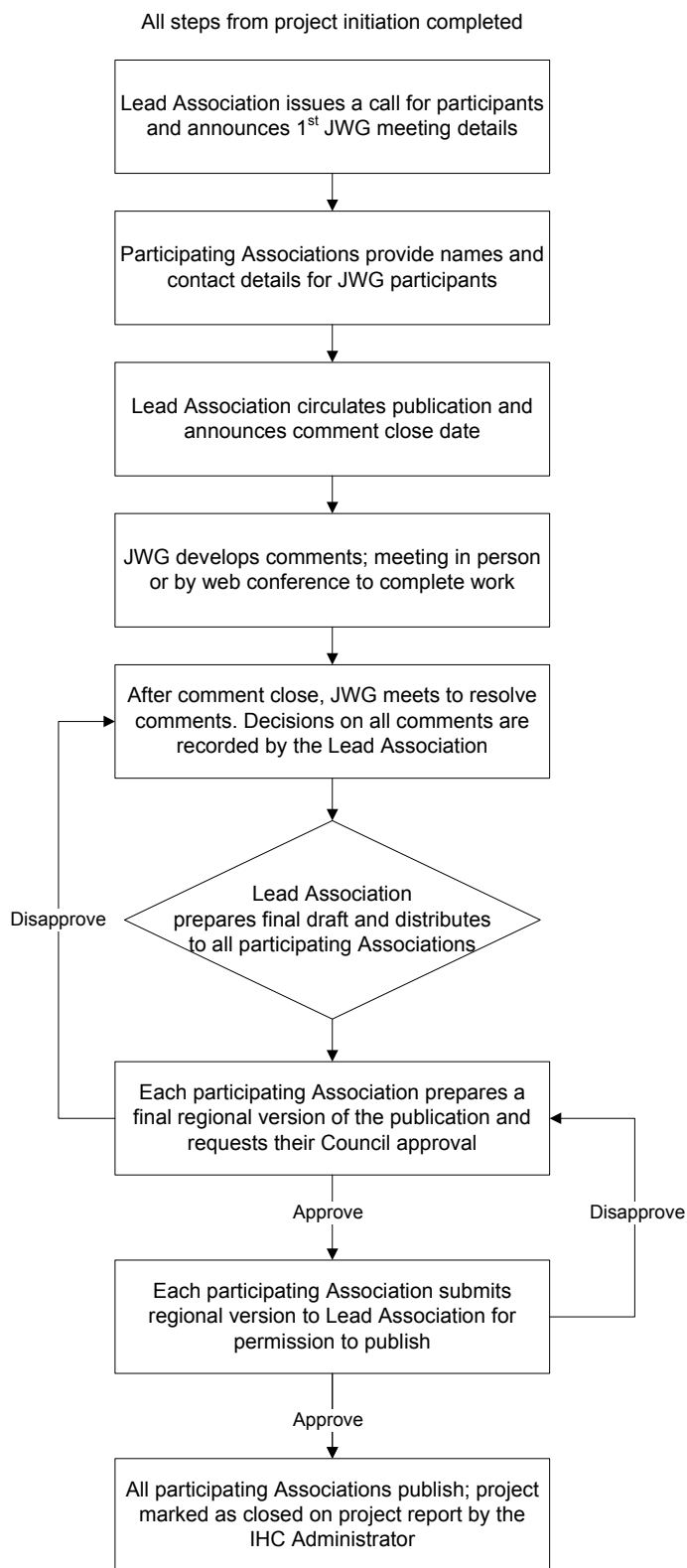
**NOTE**—Notes give additional information intended to assist with the understanding or use of the publication. No requirements or indispensable information shall be included.

**Annex N—IHC Work Process Flow Charts****Figure N-1—IHC Work Item Request approval process**





**Figure N-2—IHC Joint Working Group development of new publication process**



**Figure N-3—IHC Joint Working Group revision of existing publication process**

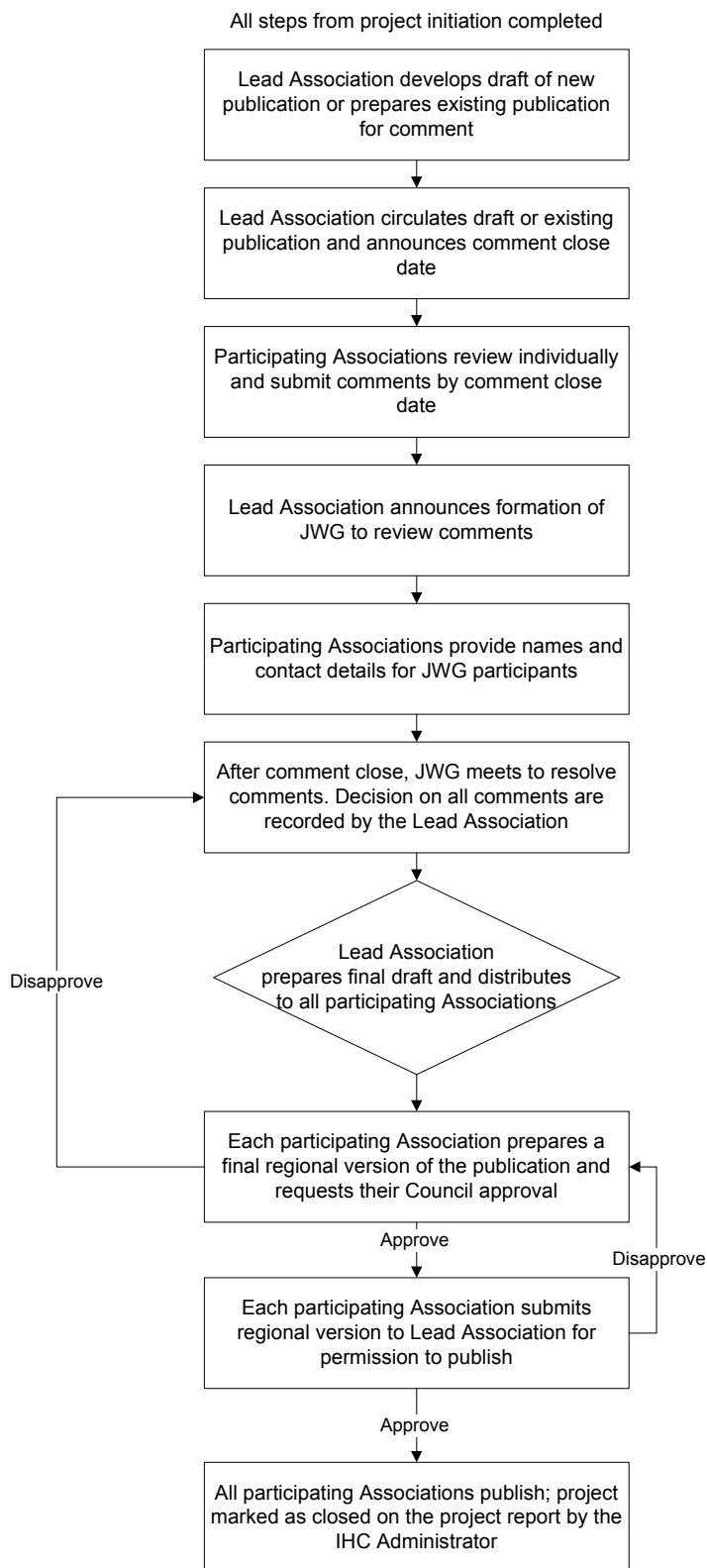
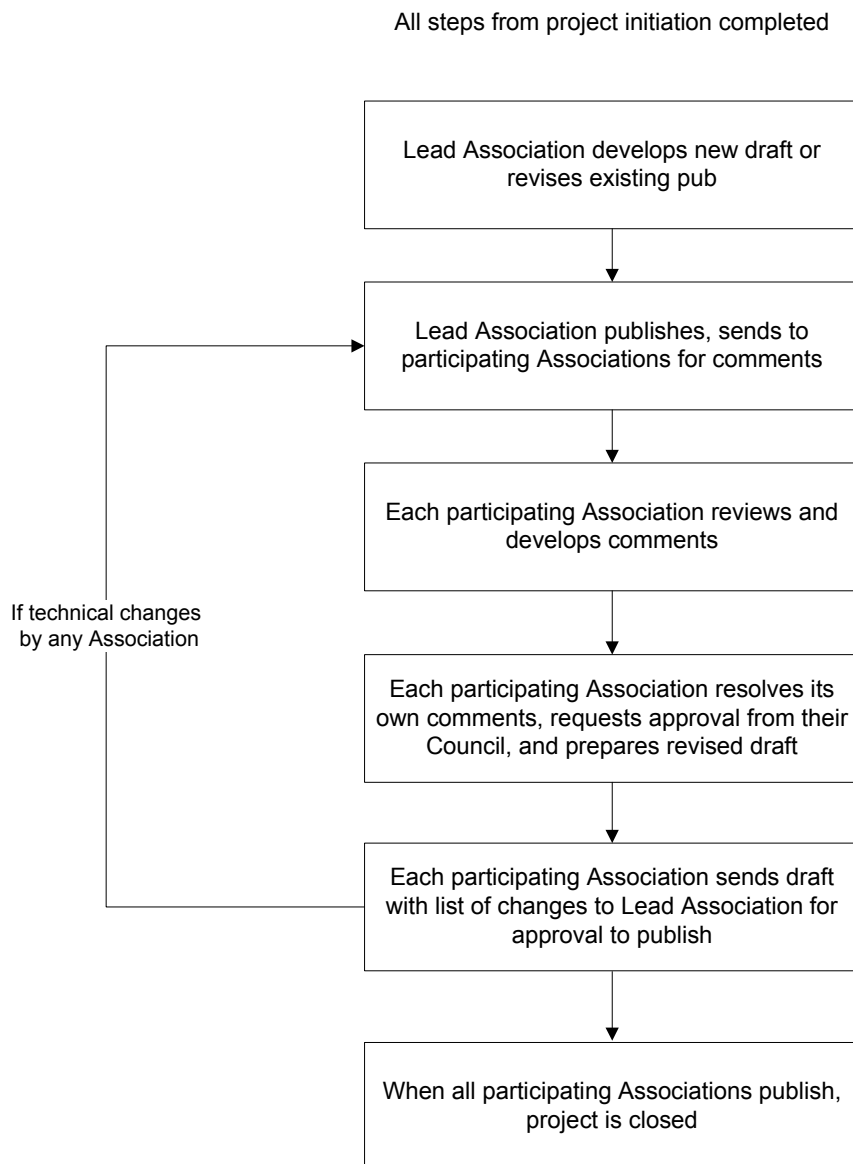


Figure N-4—IHC Joint Working Group review of comments process



**Figure N-4—IHC Lead Association process**