

International Scientific Committee of Ozone Therapy Tel/Fax (+34) 913515175. Cell Phone (+34) 669685429

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Procedures to approve ISCO3 documents

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1. Approval of papers

One of the main duties of ISCO3 is to discuss and approve draft papers which may become source of guiding and reference to all those who practice ozone therapy. It is up to each ozone therapist to follow or not the recommendations issued by ISCO3.

1.1 Types of papers to be approved by ISCO3

- 1. Administrative documents
- 2. Guidelines documents
- 3. Global reference document: Madrid Declaration on Ozone Therapy

1.2 Initiative to write down a paper

The governing body (president, vice president, secretary) or any other ISCO3 member may propose a subject for a paper. A list of papers is already included in the ISCO3 2015-2020 working plan (copy attached). The governing body shall decide if the proposal is accepted. If so, the president shall appoint a member to draft it, taking into consideration, among other points, expertise of the member on the subject, the priorities that ISCO3 may have at that particular moment, and the timing for discussion and approval.

The appointed member (drafter) has the duty to accept it, unless it may have serious and founded obstacles preventing him of accepting it. The president after assessing the reasons of the member may accept or reject them.

1.2 General Procedure

The procedure is divided into the following periods:

- 1. Proposal for drafting a paper
- 2. Appointment of a drafter by the president
- 3. 1st. drafting period
- 4. Discussing period
- 5. 2nd. drafting period
- 6. Voting period

2. Procedure for administrative documents

Administrative documents are those that relates to standards functions or activities, such as presentation of reports, CVs, forms, looking for good guidance practice, etc.



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An administrative document shall be drafted, discussed and approved directly by the governing board with no intervention of any other member. As per article 11 of ISCO3 by-laws to be approved it must be adopted by a majority of votes of the members of the Governing Board taking part in the meeting. Blank votes shall not be taken into account. In the event of a tie the President shall have the casting vote.

3. Procedure for drafting, discussing and approving guidelines documents (SOP)

Guidelines documents are those that the committee pretends that may become source of reference for those who practice ozone therapy around the world and source of moral authority at the scientific level.

3.1 Drafting period

The drafters have the authority to work alone or to create a working group set up by other members of the committee and / or ISCO3 experts and/or other persons. As described in: ISCO3/LEG/00/03 Rules & Procedures of the Council of Experts - Expert Committees Selection. However, the sole responsible before the committee shall be the drafters who are the experts.

Within the deadline given for the president the drafters shall send the 1st. draft to the secretariat that shall register the date of reception.

3.2 Discussing period

With the consent of the president the 1st. draft shall be copied to all members of the committee who shall provide their comments on the draft within the period of time assigned by the president.

Members shall send their comments directly to the drafters with copy to the secretariat, and to all ISCO3 members in the event they wish to share their comments for further discussion. The drafters have the duty to discuss directly with those who have contributed with comments and/or address all ISCO3 members who may have additional comments not previously considered. A copy of the discussions shall be sent to the secretariat. It is of the utmost importance that the drafters receive comments from members of the committee and at the same time those who have contributed to the discussion feel that their comments have been duly been taken into consideration. Nevertheless, it is up to the drafters whether or not to include in their drafts the comments received because they are the experts. In the event suggestions or comments are refuted by the drafters, and upon their sole discretion, they may choose to explain the reason(s) behind their final decision and to strengthen the overall scientific content of the draft.

Within the deadline given for the president the drafters shall send the 2nd. draft to the secretariat that shall register the date of reception.



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3.3. Voting period

With the consent of the president the 2^{nd} draft shall be copied to all members of the committee who shall vote in favor or against the draft within the period of time assigned by the president. As per article 21 of ISCO3 by-laws the draft must be adopted by a majority of votes of the members taking part in the voting. Blank ballot-paper shall not be taken into account. In the event of a tie the president shall have the casting vote.

3.4 Deadlines

Deadline for the 1st. draft paper

Depending on the subject the president shall decide the period of time that the appointed member shall have to present his first draft which shall be between a minimum of one month and a maximum of six.

Deadline for discussing the 1st. draft paper

All members of the committee shall provide their comments on the draft within the period of time assigned by the president that shall be between a minimum of one month and a maximum of two.

Deadline for the 2nd. draft paper

The drafter shall present a second draft, if necessary, within the following month after receiving the inputs from the committee members.

Deadline for voting the 2nd. draft paper

All members of the committee shall vote in favor or against the draft within the period of time assigned by the president that shall be between a minimum of fifteen days to a maximum of thirty.

Final version

At the end of the voting process, if the draft document is approved, a final version will be send to all members and experts by e.mail, posted in the official ISCO3 web site and stored in the ISCO3 virtual library. If the draft document is not approved, a new period of discussion will be stablished.

All members are responsible for spreading, using and promoting the different documents approved by the committee.



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4. Procedure for drafting, discussing and approving the Madrid Declaration on Ozone Therapy

The ISCO3 board member will be designed a drafting committee (drafters) to up-date the Madrid Declaration (MD) on Ozone Therapy. They have the authority to consult during the drafting process other members, ozone associations and /or experts of the committee and other qualified persons on the subject outside the committee. However, the sole responsible shall be the drafters committee. Drafting committee of MD will be designed two years before the expired period of the current version.

4.1 Deadlines for the Madrid Declaration on Ozone Therapy

Deadline for receiving inputs from around the world

Two years before reaching the deadline of the five years term set up in article 6, g of ISCO3 by-laws, the governing body has to decide if the current Madrid Declaration on Ozone Therapy requires amendments, modification, updates or additions. If so, the governing body shall:

- a) Appoint a drafting committee of four members.
- b) Issue at least three international calls on for inviting health professionals and other experts on medical ozone around the world to present suggestions to the drafting committee to improve the declaration, fixing a deadline to present them twelve (12) months before the approval anniversary date of the current declaration by the committee.

Deadline for the 1st. draft declaration

It shall present its draft eight months before the approval anniversary date of the current declaration by the committee.

Deadline for discussing the 1st. draft declaration

All members of the committee shall provide their comments on the draft within the following month after receiving the draft.

Deadline for drafting the 2nd. draft declaration

The drafting committee shall present the new draft within the following month after receiving the inputs from the committee members.

Deadline for voting the 2nd. draft declaration

All members of the committee shall vote in favor or against the draft within the following month after receiving the new draft. In all the cases the updated version of the declaration shall be approved by the committee at least four months before the approval anniversary date of the current declaration by the committee.



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The draft Madrid Declaration on Ozone Therapy shall be adopted by the favorable vote of two thirds of the votes from all the participating members in the voting. Blank ballot-paper shall not be taken into account. In the event of a tie the president shall have the casting vote.

Example of deadlines for updating the Madrid Declaration on Ozone Therapy

The current Madrid Declaration was approved by the committee on May 10, 2015.

May 10, 2018. The governing body shall decide if the current Madrid Declaration requires amendments, modification, updates or additions. If so the governing body shall:

- a. Appoint a drafting committee of four members.
- b. Issue at least three international calls on for inviting health professionals and other experts on medical ozone around the world to present suggestions to the drafting committee to improve the declaration, fixing a deadline to present them twelve (12) months before the anniversary date of the approval of the current declaration by the committee.

May 10, 2019	Last day for health professionals and other experts on medical ozone to present their suggestions.
September 10, 2019	The drafting committee shall present its 1 st declaration draft.
October 10, 2019	All members of the committee shall provide their comments on the 1 st . declaration draft
November 10, 2019	The drafting committee shall present the 2 nd . declaration draft.
December 10, 2019	All members of the committee shall vote in favor or against the 2 nd . declaration draft.
January 11, 2020 to the end of May 2010	Printing and translating process of the Madrid Declaration.
June 2020.	Meeting for launching the 3er Edition of the MD in Madrid.

In all the cases the updated version of the declaration shall be approved by the committee at least four months before the approval anniversary date of the current declaration by the committee, i.e. January 10, 2020.



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5. Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/LEG/00/04	13/11/2017	Draft. Submitted to approbation on virtual meeting 30/11/2017	First version

6. Document Records

	Name	Title	Signature	Date
Author	Roberto Quintero	Legal advisor		13/11/2017
Co. Authors / Reviewer	Gregorio Martínez-Sánchez	Elected president Ph.D.; Pharm. D.		13/11/2017
	Fadi Sabbah	Elected vice- president D.DS.		13/11/2017
	Adriana Schwartz	Elected secretary M.D.		13/11/2017
Authoriser / Approved	ISCO3 Board 2015-2020	All members		30/11/2017