

## ISCO3 Methodology Recommendations for Professional Training in Ozone Therapy

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## 1. General remarks

<u>Name of the certificate</u>: Certification in Ozone Therapy. Levels: Basic, Intermediate, Advanced and Specialised.

<u>Goals</u>: The aim of the current document (ISCO3/HUM/00/01. Methodology Recommendations for Professional Training in Ozone Therapy) is to serve as a general guideline for harmonization of the basic and superior courses in ozone therapy. The document define the minimum content and lecture time to be covered in the formation of human resources. In addition, this document define the methods to certified courses, professors and student Diploma.

# 2. Justification of the Social, Scientific and Professional Needs. Objectives of the Certification

In recent years, ozone therapy as an effective therapeutic method has obtained greater development and dissemination. Ozone therapy is characterised by the simplicity of its application, high effectiveness, good tolerance and a low index of collateral effects. The application of ozone in medical practice was withheld for a long time due to accumulated ideas on its toxicity in relation to the high concentrations used in industry. As with any means of healing, the application of ozone therapy for medical purposes and its therapeutic success depends on different factors, including the application of good clinical practices, the degree of training of the personnel that applies it, the use of generators and adequate doses, among others. Applied under proper methods, ozone acts as a therapeutic means and shows immuno-modulating, anti-inflammatory, bactericidal, anti-viral, fungicidal, analgesic and other properties.

Every year, thousands of patients in Russia, Germany, Italy, Spain, Mexico, Cuba, Brazil, Canada, United States, Egypt and in recent times in Asian countries receive integrative treatments with ozone for ailments such as ischaemic disease (heart, brain, limbs, retina), chronic viral illnesses, gastritis, ulcerative disease, colitis, diabetes mellitus, secondary immunological deficits, purulent processes, problems of the movement support system, skin diseases and even for HIV/AIDS and cancer. Improvements are observed in the majority of the cases, as well as the absence of any indication of toxicity in the passing of the months and years after ending the treatment.

Ozone is also gaining wide acceptance in dentistry and is used as an adjunct in tooth caries, root canal therapy, gingivitis and periodontitis, as well as in other oral indications. Next to medical applications, ozone in dentistry is the second most common use in health care.

At present there are clinical and experimental studies available that allow us to outline the issues of the effective and safe application of ozone therapy. Even though there are available clinical and experimental studies that show the safety and effectiveness of ozone applications, it is necessary that added efforts be made to minimize the objections or complaints raised by medical doctors or authorities.



There are three duly-indexed scientific journals specialised in the subject: *Revista Española de Ozonoterapia* (AEPROMO, Spain), *Ozone: Science & Engineering* (Taylor and Francis, UK), *International Journal of Ozone Therapy* (Centauro, Italy). There are more than 40 national and international scientific medical associations of ozone therapy, the number of doctors that practice it in different parts of the world exceeds 30,000, which function under the Declaration of Madrid (ISCO3/QAU/00/03), a document that has managed to unify criteria and action protocols on a global level and an international scientific committee that supports this practice (ISCO3 <u>www.isco3.org</u>).

Despite the fact that ozone therapy has great therapeutic potential, and that in various cases it exceeds the possibilities of the methods that use medicines or complements them, that its use is simple and varied, and that economically it exceeds other therapeutic methods, healthcare systems do not have sufficient information on this subject. It is in this direction, the training of qualified human resources, that this course is focused in order to raise the level of excellence of its medical practice.

## 2.1 General Objective

The academic objective of this guideline is define the minimum curriculum that permit: To lay the foundation of the basic mechanisms that justify the medical use of ozone with a view to selecting the procedures that allow its application in clinical practice.

The training objective is to define the minimum practical abilities that permit the preparation of human resources for the practice of ozone therapy on the basis of solid scientific knowledge.

## 3. Profile of the Graduate

At the end of the course the professional will be capable of acting in the clinical fields, carry out a set of therapeutic, research or integrative actions, directed to treat specific disorders depending on their area of competence: physicians, veterinarians and dentists entering into clinical research in the area of ozone therapy.

## 4. Requisites for Obtaining a Certification

## 4.1 Required Degree

To be a graduate in medicine (general or specialised doctors), dental medicine and veterinary, that carry out their functions, basically, in the field of clinical care or research in human or animal health. Any other professional interested in receiving ozone-therapy training (not M.D.) such as nurses, podologist, pharmacist and biologist would work under the direct direction and supervision of a medical doctor, who is the only responsible of the implementation of this therapy. In this case, this type of professionals may receive basic training specifying that they cannot perform this therapy alone.



## 4.2 Documentation Requirements

<u>For certification of courses</u>: Person in charge should send to the ISCO3 secretary for it evaluation the information described in the Annex I. For course certification all 100 % of professors of the course should be certified. Certification should be renew if the lectures subject was modified in more than 20 % of course approved or in case of 50 % of variation of the teaching staff. Certification can be revoke if the conditions of certification are not fulfilled.

The certification of the course should be obtained in the following levels:

- **Standard course**: The course fulfilled the minimum content established in this document, all professor obtain the ISCO3 certification.
- Advanced course: Fulfilled the condition of the standard course, plus: 1) all student get the ISCO3 certification. 2) The course will be developed under the approval of the scientific committee of an international or national ozone society.
- **Excellence Course**: Fulfilled the condition of the advanced course plus: 1) the course should be developed under University approval or approved by specialized organization in medical formation (foundation, private medical school) 2) all the teaching staff should have a medical degree of specialist or scientific degree of Ph.D. 3) Practical training should take place in certificate medical facilities.

<u>For certification of professors</u>: Professor should send to the ISCO3 secretary for it evaluation the information described in the Annex II. The curriculum of the professor (according ISCO3/QAU/00/07) should be evaluated. Professor certification should be obtained in the following levels:

- **Lecturer**: 3 years of demonstrated expertise in ozone therapy, teach part-time (5% of the lecture time of the course) but have few or no research papers.
- **Senior Lecturer**: 5 years of demonstrated expertise in ozone therapy, teach full-time (10 % of the lecture time of the course), master degree or expert diploma in ozone-therapy.
- Associate Professor: 10 years of demonstrated expertise in ozone therapy, teach fulltime (more than 10 % of the lecture time of the course). Training in pedagogic sciences, five published paper in ozone therapy, performing and leading advanced research in their fields, mentoring graduate students in their academic training, assessing students in their fields of expertise.
- **Full Professor**: Ph.D. or specialist degree, >10 years of demonstrated expertise in ozone therapy, teach full-time (more than 15 % of the lecture time of the course). Develop the curricula for the ozone courses, diploma in pedagogic sciences, > 5 paper in ozone therapy, performing and leading advanced research in their fields, mentoring graduate students in their academic training, assessing students in their fields of expertise.



<u>For certification of students</u>: Student should send to the ISCO3 secretary for it evaluation the information described in the Annex III. The curriculum of the student (according ISCO3/QAU/00/07) and the examinations approval certificate (to be sent by the teacher in charge of the organization of the course). Diploma certified by ISCO3 will be identified by stamp attaché to the Diploma. A record of graduate student in certified curse will be posted in the ISCO3 web side.

Student certification should be obtained in the following levels:

**Experts in ozone therapy**: Successful completion of the modules Basic, Intermediate and Advance.

**Specialist** (in a particular field) **in ozone therapy:** Expert in ozone therapy who acquire particular skills in a particular field of specialization by coursing and approved of specialized module.

#### 4.3 Evaluation System

The appropriation of knowledge will be evaluated, for the Basic and Intermediate Modules, by means of an integrating exam with recognition questions included within the number of class hours. For the Advanced Module, there will be a seminar (course work) which will consist of the discussion of clinical cases or of a scientific article.

The certification is made up by three individual levels of articulated learning, which provide the professional with the knowledge necessary to be able to apply this therapy with safety, without risks, allowing the greatest benefit possible for the patients. The three levels have an independent evaluation and can be taken consecutively, always progressing, or with a maximum interval of one year from having passed the lower level.

The courses for the specialised level are post-graduate courses, with independent certification and access only for the professionals of the particular branch. The evaluation in this case will be done by the publication of a scientific article on the specific theme that is the subject of the specialisation.

The practical training must be done within clinical controlled environment, preserving all the sanitary requirements of the country where the course is performing. All the material use during the instruction must be ozone resistant and follow the Madrid Declaration on Ozone Therapy (ISCO3/QAU/01/03) guidelines.



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## 5. Curriculum

## 5.1 General

The following curriculum proposal will be consider the minimum subjects to be treated in the different courses.

	Class time (hours)	
	Practical	Lon distance
	Classroom	education*
Davia Madula	Activities	20
Dasic Mouule	14	30 5
History of ozone therapy. Introduction to it	1	5
and its future projections.	1	-
Legal framework	l	5
Ozone generators: use and requirements	4	3
Reactive oxygen species and redox environment	2	10
Biochemical and biological bases of the ozone	2	10
Preclinical, clinical and toxicological evidence	2	5
Evaluation	2	
Intermediate Module	57	90
Clinical evidence of the effects of ozone	1	10
Routes of administration in ozone therapy	8	15
Clinical protocols in ozone therapy	4	10
Redox environment and diseases	5	10
Ozone therapy in orthopaedics and traumatology	15	15
Ozone therapy in Internal Medicine	15	15
Ozone therapy in Gynaecology**	5	10
Ozone therapy in Paediatrics**	2	5
Evaluation	2	
Advanced Module	16	55
Good clinical practices. Design of clinical studies	2	5
Complementary techniques	4	10
Integrated practices***	10	10
Course paper****	0	30
Total (to achieve the diploma)	87	183
Total General		270

Notes:

\* They will be complemented in the form of independent study on the contents that are being given.

\*\* Elective subject, depend of the field of expertise of the students.

\*\*\* Integrated practices in routes of administration and general procedures in ozone therapy.

\*\*\*\* The course work constitutes the student's final examination, consisting of the discussion of clinical cases or of a scientific article. The publication of a bibliographic or experimental article in a peer-reviewed specialised scientific journal will also be considered.



## 5.2 Basic Module

**Rationale.** This course allows the professional to have the primary bases for the safe handling of ozone, to know how it is generated and to be able to calculate the volumes, concentrations and doses that are required to be used in its application. It begins with the historic precedents, legal status in the world and brings together basic subjects that will lead to an understanding of the action mechanism and to support its pharmacological properties as well as the toxicological aspects.

**Objectives:** To have a thorough knowledge of the historical premises, state of knowledge and legal framework, the basic physical characteristics of ozone, its existence in nature, its toxicity and the essential care that one must take in manipulating it, the use and handling of the different generators of the gas, their accessories and the way to mathematically calculate the dose that will be applied to the patients. A comprehensive grasp of the elemental biochemical bases for the understanding of the pharmacological and toxicological action mechanisms of ozone, and the pre-clinical and clinical experimentation that supports its applications are also the objective of this module.

## 5.2.1 Contents of the Basic Module Subjects

## **Introduction to Ozone Therapy**

**Contents:** Ozone, discovery, chemical and physicochemical characteristics. Ozone in nature. Half-life in nature, decomposition and artificial destruction. Historical aspects linked to clinical applications. The first generators and their evolution. Emergence and contribution of the principal schools of ozone therapy in the world. Evolution of scientific knowledge on the action mechanism of ozone therapy. Principles for the correct application of ozone therapy.

## Legal framework

**Objectives:** Getting to know the legal development that ozone therapy has had in the world, and the specific legal status in the countries where it is implemented. Becoming familiar through a comparative legal analysis on the advances obtained in the subject of regularisation. Knowing the legal tools that could be used in the request for regularisation. Medical-legal requirements for operating with ozone in a medical office.

**Contents:** Authorities and ozone therapy. Elite sports and ozone therapy. Courts and ozone therapy. Research and ozone therapy. Prohibition and prosecution of ozone therapy. Legal backwardness and ozone therapy. To regularise or not to regularise. Russia. Cuba. Spain. Italy. Germany. United States of America. The FDA and ozone. States with laws of healthcare freedom. Mexico, Chile, Colombia. Portugal. Honduras, Turkey, among others. Legal strategies for regularisation. Political-administrative structure of the State. What legal formality should regularisation have? What should the



format of the ideal regularisation be? Importance of the comparative analysis of the law. International legislation applicable to ozone therapy. Helsinki Declaration. Madrid Declaration on Ozone Therapy (ISCO3/QAU/01/03). Non-conventional medicine and the Parliamentary Assembly of the European Council. Lobbying.

#### **Ozone generators**

**Objectives:** To identify and interpret the principal indicators of quality of medical ozone generators.

**Contents:** Functioning principle of the generators. Mandatory requirements for the acquisition of a generator. Production and types (grades) of oxygen. Sources of oxygen for ozone therapy. Flow and concentration indicators. Calculation of the concentrations and doses of ozone. EC certification of the generators. Calibration and quality control. Applications of the equipment (local production of ozonized water, ozonized oils, working in continuous cycle). Care and safety measures. Operating procedures and aseptic conditions. Destroyers of ozone and their function. Other equipment that is connected to the generators (peristaltic pumps, UV lights, saunas, equipment for continuous extracorporeal ozonization). Environmental effects on the concentrations of ozone. Description of the concentrations of ozone and their effect on different materials. Materials required in the production of components for systems that use ozone. Risks of working with unsafe equipment. Peripheral accessories. Insufflation bags. Accessories for ear and nasal insufflation (after bubbling in olive oil). Accessories for dental applications, other accessories.

#### **Reactive Oxygen Species and Redox Environment:**

**Objectives:** Identify the essential features of the ROS generating and inactivating systems.

**Contents:** Basic concepts on the redox imbalance and the Reactive Oxygen Species. ROS sources or generating mechanisms. Interaction of the ROS with cell components. Damage to the macromolecules modified by ROS. Consequences of their attack. Antioxidant mechanisms. Evidence that shows the participation of ROS on different physio-pathological conditions.

#### **Biochemical Bases of the Effects of Ozone**

**Objectives:** Recognise the basic biochemical and molecular mechanisms through which ozone therapy operates.

**Contents:** Basic concepts on hormesis and dose-response ratio. Redox diagnosis and its link to ozone therapy. The oxidative preconditioning, ozone as modulating agent of oxidative stress. Mechanisms of the action of ozone in pain. Mechanisms that justify the autoimmune effects of ozone. Delivery of oxygen to the tissues by ozone and its bases. Germicidal effects of ozone and its derivatives (oil and water). Effects of ozone on the



release and/or synthesis of autacoids. Ozone as a metabolic regulator. Other mechanisms associated with the applications of ozone.

## Preclinical, Clinical and Toxicological Evidence

**Objectives:** To have a thorough knowledge of the scientific evidence related to toxicity and the preclinical and clinical bases associated with ozone therapy.

**Contents:** Ozone as an environmental contaminant, pulmonary targets, incidence of respiratory and cardiovascular diseases and fatality. Exposure and safety limits. Toxicological studies on ozone. Disease models and pre-and post-oxidative conditioning results. Clinical evidence of meta-analysis studies and other published clinical studies.

## 5.2.2 The Teaching Strategy and Means Used in Teaching

Designed so that students will acquire basic knowledge that gives them security in what they will see and do in practice within the course itself. There will be videos, photographs and other audio visual media. During the course, students will be guided on the study methods and the documents, books, journals and websites to which they have access as educational material for consultation. They will also handling practices on the generators and will have the opportunity to interact with the teacher directly.

## 5.2.3 Evaluation

Taking into account the importance that this Basic Module has for the professional that recently began to learn about this therapy, a theory exam is given at the end of the module to discover whether the students have acquired the required knowledge. Students must obtain a grade of 70/100, otherwise they cannot begin the Intermediate Course.

The exam may be multiple choice, which will make it possible to know whether the student understands the basic concepts; it will include all the basic subjects dealt with in this level. Students who do not pass the exam may be given a review, they will revise and retake the exam.

#### 5.3 Intermediate Module

**Rationale:** This level contains the principal technical and theoretical elements in order to understand the biochemical and clinical bases of the invasive and non-invasive applications of ozone therapies, which make it possible for the professional to understand how and through what mechanisms this gas acts in the body. Clinical protocols are addressed to orthopaedics/traumatology, internal medicine, gynaecology and paediatrics, as these specialities occupies the largest field of the application of ozone.



**Objectives:** To have a thorough knowledge of the biochemical and clinical bases that will lead to understanding the specific and particular mechanisms through which ozone acts at the local and systemic level, while learning the particular actions that this gas may exercise in different systems and organs of the body and in particular in the osteo-muscular system, as well as its short- and long-term effects. To master the knowledge related to the protocols of clinical application and the characteristics of the application routes.

## 5.3.1 Objectives and Contents of the Intermediate Modular Subjects

## Medical Indication and Clinical Evidence of the Effects of Ozone

**Objectives:** To understand the clinical evidence on scientific bases related to ozone therapy.

**Contents:** Ozone and its general applications. Effects of ozone on internal medicine, pain therapy, urology, gynaecology, ophthalmology, traumatology, orthopaedics, immune system diseases, cancer, cardiovascular and neurodegenerative diseases. Ozone in the treatment of ulcers and other lesions and as adjuvant in surgical treatments. Application of ozone in other medical specialities.

#### **Administration Routes in Ozone Therapy**

**Objectives:** To have a thorough knowledge of the administrative routes of ozone therapy, the standard operating procedures to follow, dosage regime and frequencies of application for each case.

**Contents:** Recommended routes for the local administration of ozone therapy, unsuitable routes. Systemic administration routes appropriate for the application of ozone therapy, unsuitable routes. Therapeutic applications of each route, practical demonstration, standard protocols for each procedure. Safety measures for operating with ozone. Safety measures in view of emergencies, emergency first aid kit. Applications of: ozonized water, suction cups and ozone bags (for limbs), saunas, ear, rectal and vaginal insufflations. Major Autohaemo-Therapy (MAHT) and Minor Autohaemo-Therapy (MiAHT), ozonized saline solution. Use of ozonized oil according to its peroxidation index.

#### **Clinical Protocols in Ozone Therapy**

**Objectives:** To identify the procedure for establishing the dosage and frequencies of personalised application according to the clinical case.

**Contents:** Basic diagnostic principles, anamnesis of the patient. Oral and written informed consent. Physical examination. Support with images or results from the clinical laboratory. General protocols of treatment per medical speciality. Guidelines to



follow in ozone treatments. Therapeutic ozone concentrations. Adaptation of the general protocols to specific cases. Analysis and discussion of actual cases. Adverse events and first aid procedures. Primary indications. Secondary indications. Limits and myths of ozone therapy. Contraindications. The role of ozone as a therapeutic complement.

#### **Redox Environment and Diseases**

**Objectives:** To Appropriate of knowledge that allows the identification of the physiopathological Redox condition that contribute to the emergence of diseases and mortality.

**Contents:** Redox molecular mechanisms associated to Cardiovascular Diseases: Myocardial and Cerebral Infarction, High Blood Pressure and Atherosclerosis; to the Immune System: Cancer (colon, prostate and lung), HIV; to autoinmune diseases: Rheumatoid Arthritis, Lupus; to Endocrine System: Diabetes and its complications (nephropathy and neuroinfectious foot) and Aging degenerative diseases: Parkinson, Alzheimer and senile dementia.

#### **Ozone Therapy in Orthopaedics and Traumatology**

**Objectives:** The appropriating of knowledge that allows application of ozone therapy in the specialty of orthopaedics and traumatology.

**Contents: Cervical Spine:** Clinical condition, Physical and neurological examination, Suitability of the use of ozone in the cervical spine. Infiltrations in cervical spine with ozone. **Lumbar Spine:** Physical and neurological examination. Suitability of the use of ozone in the lumbar spine. Action mechanisms of ozone in the spine. Intramuscular, facet joint, foraminal, peridural, sacroiliac infiltrations. **Knee:** Physical examination and exploratory diagnostic manoeuvres. Suitability of the use of ozone in knees. Dosage. Technique and approaches for infiltration of the knee. **Hip:** Physical examination and exploratory manoeuvres. Suitability of the use of ozone. Dosage. Technique and approaches for infiltration of the hip. **Shoulder:** Physical examination and exploratory manoeuvres. Suitability of the use of ozone. Dosage. Technique and approaches of the hip. Shoulder: Physical examination and exploratory manoeuvres. Suitability of the use of ozone. Dosage. Technique and approaches of the hip. Shoulder: Physical examination and exploratory manoeuvres. Suitability of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone. Dosage. Technique and approaches of the use of ozone.

#### **Ozone in Internal Medicine**

**Objetives:** The appropriating of knowledge that allows application of ozone therapy in the specialty of internal medicine.

**Contents:** The analysis of the physiopathology and treatment with ozone of: **Metabolic diseases:** Diabetes Mellitus, metabolic syndrome, obesity, atherosclerosis, hypercholesterolemia, hypothyroidism. **Cardiovascular diseases:** Myocardial and Cerebral Infarction, High Blood Pressure. **Autoimmune diseases:** Arthritis rheumatoid, Lupus, psoriasis, atopic dermatitis. **Urinary tract diseases:** ITUS, glomerulonephritis and chronic renal failure. **Gastrointestinal tract diseases:** Chronic Gastritis



(Helicobacter Pylori), Diverticulosis, Cronh disease, ulcerative colitis, hemorrhoids, constipation. **Respiratory tract diseases:** Asthma, bronchitis, EPOC.

## **Ozone in Gynecology**

**Objectives:** The appropriating of knowledge that allows application of ozone therapy in the specialty of gynecology.

**Contents:** The analysis of the physiopathology and treatment with ozone of: endometritis, recurrent vulvo-vaginitis, bacterial and fungal vaginoses, vulvar craurosis, menopause syndrome, infertility, inflammatory diseases of the annexes of the uterus, Papilloma Virus infection, VIH, trichomonas. Effect of ozone therapy on the immune status of women with miscarriage.

## **Ozone in Pediatrics**

**Objectives:** The appropriating of knowledge that allows application of ozone therapy in the specialty of pediatrics.

**Contents:** The analysis of the physiopathology and treatment with ozone of: Spastic cerebral palsy, achondroplasia, infections of ORL, asthma, tonsillitis, otitis.

## 5.3.2 The Teaching Strategy and Means Used in Teaching

At this level the student must already have a good knowledge of the therapeutic action mechanisms of Ozone, as well as of its applications in medicine. As an example and to make this part of the course more understandable and pleasant, slides of the complete metabolic pathways where one can see the precise places in which the ozone metabolites work, discussing in detail its action on the molecular level. The clinical part is supported with photos of treated patients, videos of applying the therapy and also testimonies of some patients. In classroom courses this level will has 30% of practical hours through direct video transmissions of demonstrations in actual patients, practices in simulators, videos and application examples.

#### 5.3.3 Evaluation

As a result of the paramount importance that this part of the Certification has for the professional, after finishing it a multiple choice exam will be given as accreditation of the Intermediate module and which makes it possible to know whether the required knowledge has been acquired in order to continue to the Advanced Level. The exam will have 100 points and to pass 70 points will be necessary. As occurs at the end of the Basic Course, students who do not pass the exam will be given a review, they will revise and retake the exam.

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#### 5.4 Advanced Module

**Rationale**: Students must learn how to integrate ozone therapy with other therapeutic modalities and diet management. In addition, they need to know the basic elements of good clinical practices and of scientific wording. With this knowledge the professionals will be in a condition to offer a service of excellence and in a condition to publish and make known their own clinical experiences.

**Objectives:** To integrate the basic knowledge of ozone therapies, taking advantage of the synergistic effects of the protocols of ozone therapy with other therapeutic modalities. To have a thorough knowledge of the bases of good clinical practice and of the scientific method.

## 5.4.1 Objectives and Contents of the Subjects of the Advanced Module

#### **Good Clinical Practices. Design of Clinical Studies**

**Objectives:** The appropriation of knowledge that allows implementation of good clinical practices to ozone therapy, as well as to disclose scientifically the results.

**Contents:** Main concepts on good clinical practices. Ozone and clinical studies. Obtaining scientific information (presentation of the guide books and the Zotero ISCO3 database). Bases of scientific writing. Design of clinical studies. Main concepts and applications to ozone therapy.

#### **Complementary Techniques**

**Objectives:** The appropriation of knowledge that allows application of ozone therapy in combination with other techniques: Growth factors, ozonized platelet-rich plasma (PRP), UV light, diet management.

**Contents:** PRP: History of PRP. Basic aspects of platelets and growth factors. Aggregation and activation processes. Indications and contraindications. Obtaining and preparation of the PRPO3. Applications in traumatology and ulcers. Informed consent. UV light: history, action mechanisms, therapeutic effects, discussion of clinical cases. Diet and nutritional supplements: interaction of exogenous antioxidants and ozone therapy, diet and ozone therapy. Appropriate handling.

#### Practice

**Objectives:** To acquire practical skills in the techniques of preparation and application of ozone, as well as the handling of clinical protocols.

**Contents:** Performing the techniques of ozone preparation, ozonized water and oils. Ozone administration through local and systemic pathways. Performing with real clinical cases. Infiltration techniques in orthopaedics and blocking in pain management.



## 5.4.2 The Teaching Strategy and Means Used in Teaching

At this level of the Certification, the principal aspect is for the student to work with cases of patients treated with ozone therapy, whether in photos, with slides, with videos, with recorded or live testimonies.

At the same time students will see how the applications are made with ozone in painful joints or in other places in real patients and simulators. Applications can be made in the students themselves that present any problem that is susceptible to being treated with ozone. The doctors themselves guided by the professors may also perform some interventions as a form of learning, which will give them security for upcoming interventions when they are in their own work areas, whether public or private. Students will be shown how ozone therapy is integrated with complementary techniques such as PRP, UV light and they will be shown how diet should be managed. This module is eminently practical: 70% of the allocated time.

#### 5.4.3 Evaluation

At the end of the course it must be evaluated whether or not the students have acquired the required knowledge to apply ozone therapy correctly and safely to the patients. It must be clarified whether or not the students passed the exams corresponding to the Basic and Intermediate Courses since they contain the fundamental bases for the proper handling of the therapy. The advanced module is more of clinical applications, therefore what will be evaluated more in this case is the performance that the doctor presents in this regard. The evaluation will be done through the discussion of a clinical case, alternatively the student may present a scientific paper reporting a case, bibliographical review or research. At the end of this module the student is considered certified.

## 5.5 Specialised Module

**Rationale:** This module constitutes the higher level of the student's specialisation. They are courses directed at training experts in ozone therapy in a certain medical speciality. By requiring very particular skills and knowledge, they will be aimed at a specialised professional sector. This module requires the previous diploma of expert in ozone-therapy and is not part of this course.

**Objectives:** To master the techniques and methods of applying ozone therapy in a certain speciality.



## 5.5.1 Specialization Courses

Specialized coursed will be organized for the student graduated as *Expert in Ozone Therapy*. The content of the coursed will be designed by expert in the corresponding area of specialization. The following course are examples of titles and content of some of the most important field of specialization in ozone therapy. Minimal curriculum will involve no less than 25 h classroom lecture and 75 h long distance education.

# 1) Use of Ozone and Concentrated Growth Factors (CGF) in Degenerative Discal Pathology and Herniated Nucleus Pulposus. Radicular Compression Syndrome.

Lumbar spine anatomy. Functional units of the lumbar vertebral spine: lumbar vertebrae, intervertebral discs, ligaments, muscles, nerve roots. Biomechanics of the lumbar spine (the lumbar rachis). Mobility of the lumbar spine: Intervertebral disc. Function of the nucleus pulposus. Lumbosacral articulated joint. Sacroiliac joint. Third lumbar vertebra and twelfth dorsal vertebra. Degenerative disease of the lumbar intervertebral disc. Epidemiology. Discal degeneration. Herniation of the nucleus pulposus. Clinical condition and physical examination. Diagnosis. Treatment: conservative. Pharmacology and Rehabilitation. Therapeutic blocks. Surgery (classic, endoscopic). Ozone therapy. Degenerative narrow lumbar channel. Anatomy. Natural history. Clinical condition and physical examination. Diagnosis: Treatment: conservative. Pharmacology and physical rehabilitation. Therapeutic blocks. Surgery (classic, endoscopic). Ozone therapy. Procedures for the application of ozone in a degenerative spine. Paravertebral (one level, multiple levels). Facet joints. Foraminal. Caudal. Intradiscal.

#### 2) Ultrasound-guided Injection Techniques with Ozone in Painful Joints.

**Shoulder:** Injection of the subacromial space – posterior approach. Glenohumeral joint. posterior approach. Glenohumeral joint - anterior approach. Acromioclavicular joint. **Elbow:** Elbow joint. Olecranon bursitis. Lateral epicondylitis. Medial epicondylitis. Cubital tunnel syndrome. **Wrist:** Carpal tunnel syndrome. Wrist joint. De Quervain's tenosynovitis. Carpometacarpal joint of the first finger. **Hip:** Injection of the hip joint. Lateral approach. Injection of the hip joint. Anterior approach. Trochanteric bursitis. **Knee:** Joint injection. Suprapatellar approach. Lateral. Joint Injection. Infrapatellar approach. Joint injection. Medial approach. Prepatellar bursitis. Anserine bursitis. Iliotibial band friction syndrome. **Ankle:** Ankle joint injection. Subtalar joint injection. Midtarsal joint injection. Peroneal tendinitis.

- **3) Ozone therapy in the treatment of Mitochondrial Diseases:** The oxidative stress "The new face of aging and illness"; The mitochondriopathies "A challenge for modern medicine"; Ozone therapy as auxiliary in mitochondrial therapy; The cost of the diagnostic error in the mitochondrial pathology; Clinical cases.
- 4) Ozone therapy and Concentrated Growth Factors (CGF) in aesthetic medicine: Properties of C.G.F. Blood extraction, Preparation, and different techniques of infiltration.
- 5) **Prolozone:** Indications, contraindications, preparation and application techniques.



- 6) **Ozone-UV-light:** Management and Equipment. Technic, indication and contraindications.
- 7) Ozone therapy in Ophthalmology.
- 8) Ozone therapy in Dentistry (for dentists)
- 9) Techniques of ozone therapy application in small-sized animals (only veterinarians)

#### 6.0 Bibliographic Support

- > It is suggested the following text book as basic references:
- Books and paper listed in ISCO3/QAU/00/19. Ozone Therapy and its Scientific Foundations.
- Edward Lynch. Ozone, the Revolution in Dentistry. Quintessence Publishing Co Ltd (2004). ISBN 1-85097-088-2
- ISCO3/QAU/01/03. Madrid Declaration on Ozone Therapy 2015-2020 Eng. Schwartz-Tapia A, Martínez-Sánchez G, Sabah F, Alvarado-Guémez F, Bazzano-Mastrelli N, Bikina O, Borroto-Rodrígez V, Cakir R, Clavo B, González-Sánchez E, Grechkanev G, Najm Dawood A H, Izzo A, Konrad H, Masini M, Peretiagyn S, Pereyra, V R, Ruiz Reyes D, Shallenberger F, Vongay V, Xirezhati A, Quintero-Marino, R. Madrid Declaration on Ozone Therapy. 2th ed. Madrid: ISCO3; ISBN 978-84-606-8312-4; 2015. 50 p.
- As additional bibliographical support there is the electronic data base of the ISCO3, mounted on the ZOTERO system, of free on-line consultation which contains at present more than 2,000 bibliographical references on the subject: <a href="http://www.zotero.org/groups/isco3\_ozone">http://www.zotero.org/groups/isco3\_ozone</a>

➢ Furthermore, the following specialised journal is recommended for consultation: Revista Española de Ozonoterapia (official AEPROMO journal): <u>http://www.revistaespañoladeozonoterapia.es/index.php/reo</u>

## 7.0 Teaching Staff

The teachers of this certification must be professionals with broad (demonstrated) experience as teachers, as physicians and researchers who meet all the requirements of capacity, ethics and basic training in order to teach the course. Requiring as far as possible that they have university training in ozone therapy. A summary of the faculty's résumés will be recorder by the person in charge. It is suggested the use of the template ISCO3/QAU/00/07 for the preparation of the CV summary.



## 8. Schedule and Organisation

The curses will be carried out in a period of 6 months in the long distance modality, under the guidance of the faculty of teachers who will respond to the student's questions in the period of 48 h. The questions and answers will be uploaded to an Internet platform. In addition, the student must pass 3 module of classroom guided practice. At the end of the course, the student must turn in a research paper or written presentation of a clinical case. The presented papers that comply with the requisites for international publication may be published in specialized journals.

#### 9. Continuity of the Educational Process

The certified students must continue to develop by means of individual study, consultation of the updated bibliography, as well as participating in other courses of a higher level in ozone therapy, workshops, national or international symposia and congresses. Their membership in national and international scientific societies is recommended.

The student shall bear in mind that ozone therapy is a therapeutic tool in constant development, which, therefore, requires the constant study and reviews of scientific articles and other materials in order to keep up to date in the advances in the area.

During the courses, the basic tools are given to the students for their initiation and motivation for research, given the importance that each professional may have in the development of ozone therapy, through the conducting of research and publications in the branch of work in which each one operates, becoming in this way an active participant in the progress of this therapy.

## 10.0 Cost of the Certification Program

#### **ISCO3 certification program**

The certification program of the ISCO3 will be in the following levels:

Certification of courses Certification of professors Certification of student Diploma

The applicant country, association or institution will present the program in detail to the ISCO3 for its approval, which will grant its seal of quality for carrying it out. See Annex I to III for a rapid cheeking list of the requirement of each level of certification. See point 4 of this document for details of the requirements.



The ISCO3 will make a follow up to ensure that these standards (courses quality) are met. If it is verified that the standards are not met, the organization concerned will be penalized by removing the seal and the backup of ISCO3. In this case, no refunds of any money will be done.

#### The fees for the certification will be the following:

	Developing country <sup>1</sup>	Rest of the world
Certification of courses	50 EUR	200 EUR
Certification of professors	20 EUR	50 EUR
Certification of individual	5 EUR	10 EUR
student Diploma		

Legend: 1 The classification of the developing country will be taken from the United Nation (http://www.un.org/en/development/desa/policy/wesp/wesp\_current/2014wesp\_country\_classification.pdf)

#### 11. References

#### **11.1 SOP References**

ISCO3/QAU/01/03. Madrid Declaration on Ozone Therapy 2015-2020 Eng. Schwartz-Tapia A, Martínez-Sánchez G, Sabah F, Alvarado-Guémez F, Bazzano-Mastrelli N, Bikina O, Borroto-Rodrígez V, Cakir R, Clavo B, González-Sánchez E, Grechkanev G, Najm Dawood A H, Izzo A, Konrad H, Masini M, Peretiagyn S, Pereyra, V R, Ruiz Reyes D, Shallenberger F, Vongay V, Xirezhati A, Quintero-Marino, R. **Madrid Declaration on Ozone Therapy**. 2th ed. Madrid: ISCO3; ISBN 978-84-606-8312-4; 2015. 50 p.

ISCO3/QAU/00/07. Template for *Curriculum Vitae* summary

ISCO3/QAU/00/19. Ozone Therapy and its Scientific Foundations

#### **11.2 Other References**

United Nation (2014). Country classification (http://www.un.org/en/development/desa/policy/wesp/wesp\_current/2014wesp\_country\_classification.pdf)

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## **Change History**

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/HUM/00/01	18/10/2015	Draft	First version
ISCO3/HUM/00/01	09/11/2015	Approved version	First version

## **Document Records**

	Name	Title	Signature	Date
Authors	Adriana Schwartz Tapia Adriana@aepromo.org	Elected secretary M.D. Main drafter		18/10/2015
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Authoriser / Reviewer / Approved	ISCO3 Board 2015-2020 ISCO3 Members 2015-2020	All members		09/11/2015

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## Annex I. Requirement and checking list for Courses Certification

Date: (dd/mm/yyyy) / /	Place:	
Course title:		
Organized by:		
Professor in charge:		
Address:		
E.mail.		
Phone:		
<ul> <li>Complete and submit course worksho schedule)</li> </ul>	eets (list of subjec	ets, contents, professors, time
□ Pay the assessment fee as indicated at HUM/00/01)	the certification (P	oint 10 Doc. ISCO3
Number of professors involved		
Number of professor certified by ISC be certified)	CO3 (100 % of pro	fessors of the course should
Number of professor with Ph.D. or	specialist degree	
Levels of the application □ Standard □ A Is expected and motivate the student to NO The course is developed under the international or national ozone socie If yes, name of the society (provide The course will be developed under Univ If yes, name of the university (provide Practical training take place in certificate If yes, name of the facilities (provide	Advanced   Excell get the ISCO3 Di approval of the ety?  Yes  NO documentary evide versity approval?  e documentary evide medical facilities documentary evide	ence ploma certification? □ Yes □ scientific committee of an ence): □ Yes □ NO dence): . □ Yes □ NO ence):
FOR THE USE OF ISC Course worksheets according to the gu Payment according Point 10 Doc. ISC 100 % Professors Certified according to	O3 CERTIFICAT hideline ISCO3 HU O3 HUM/00/01 to the guideline IS	<b>TION BOARD</b> JM/00/01 CO3 HUM/00/01
Levels of Certification   NO  Standard	$\square$ Advanced $\square$ Ex	xcellence
Number of the Certification: ISCO3 CO number)	<u>C YYYY SSNN</u>	(YYYY year, SSNN Serial
Revised by, Name/Surname:	Position:	Date:
Approved by, Name/Surname:	Position:	Date:



## Annex II. Requirement and checking list for Professors Certification

Date: (dd/mm/yyyy) / Place:
Professor Name / Surname:
<ul> <li>Complete and submit CV (ISCO3/QAU/00/07)</li> <li>Pay the assessment fee as indicated at the certification (Point 10 Doc. ISCO3 HUM/00/01)</li> </ul>
Levels of the application $\Box$ Lecturer $\Box$ Senior Lecturer $\Box$ Associate Professor $\Box$ Full Professor
Years of demonstrated expertise in ozone therapy:
Percent of the lecture time of the course:
Master degree or expert diploma   Yes  NO If yes, name
Ph.D. degree or specialist   Yes  NO If yes, name
Training in pedagogic science $\Box$ Yes $\Box$ NO If yes provide documentary evidence
Number of paper in ozone therapy last 10 years:
FOR THE USE OF ISCO3 CERTIFICATION BOARD  Complete CV (ISCO3/QAU/00/07) Payment according Point 10 Doc. ISCO3 HUM/00/01
Levels of Certification  □Lecturer □Senior Lecturer □Associate Professor □Full Professor
Number of the Certification: <u>ISCO3 PC YYYY SSNN</u> (YYYY year, SSNN Serial number)
Revised by, Name/Surname:Position: Date:
Approved by, Name/Surname:Position:Date:



## Annex III. Requirement and checking list for Students Certification

Date: (dd/mm/yyyy) / Place:
Name / Surname:
Course Approved:
The course is Certified by the ISCO3 $\Box$ Yes $\Box$ NO If yes, Number of certification
ISCO3 CC
Date: Edition:
Address:
E.mail.
Phone:
<ul> <li>Complete and submit CV (ISCO3/QAU/00/07)</li> <li>Pay the assessment fee as indicated at the certification (Point 10 Doc. ISCO3 HUM/00/01)</li> </ul>
Levels of the application   Experts in ozone therapy   Specialist in ozone therapy
Profession:
Field of specialization
Occupation
FOR THE USE OF ISCO3 CERTIFICATION BOARD
<ul> <li>Complete CV (ISCO3/QAU/00/07)</li> <li>Payment according Point 10 Doc. ISCO3 HUM/00/01</li> </ul>
Levels of Certification   Experts in ozone therapy   Specialist in ozone therapy
Number of the Cartification, ICOO2 CC XXXX SCNNI (XXXXX SCNNI S

Number of the Certification: <u>ISCO3 SC YYYY SSNN</u> (YYYY year, SSNN Serial number)

Revised by, Name/Surname: _	Position:	_ Date:
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Approved by, Name/Surname: \_\_\_\_\_Position: \_\_\_\_\_ Date:\_\_\_\_\_