

Guidance

on tasks and obligations of the examining body for certificates of competence for treatments using non-ionising radiation and sound in accordance with the Ordinance to the Federal Act on Protection against the Risks associated with Non-Ionising Radiation and with Sound (O-NIRSA)

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Content

1	Introduction and purpose of this guidance	3	
2	Tasks and obligations of the examining body	4	
2.1	General requirements	4	
2.2	Administrative tasks		
2.3	Organization and conduct of the training and the examination	5	
2.4	Training and examination procedures	5	
2.5	Admission requirements for training and examinations	5	
2.6	Verification of appeals	5	
2.7	Compliance with advertising requirements	6	
2.8	Issuing and notification of certificates of competence	6	
2.8.1	General		
2.8.2	Issuing of certificates of competence		
2.8.3	Notification of persons with certificates of competence in the ePortal NIRSA	7	
2.9	Removal of persons from the ePortal NIRSA following the revocation of certificates of		
	competence		
2.10	Evaluation of training courses and examinations		
2.11	Annual reporting of examination statistics		
2.12	Notification and submission of changes		
2.12.1	Changes in personnel		
2.12.2	Changes in the content of teaching materials, teaching plans, examination questions, etc		
2.12.3	Substantial changes in content		
2.12.4	Change of name of the examining body		
3	Periodic reviews by the FOPH	10	
3.1	Current state of knowledge and technology five-year review		
3.2	Case-by-case review		
3.3	On-site inspections	10	

1 Introduction and purpose of this guidance

In order to be listed as an examining body in the Annex of the FDHA Ordinance on certificates of competence for treatments for cosmetic purposes using non-ionising radiation and sound of 24 March, certain tasks and obligations must be fulfilled. These must be understood and adhered to. For this reason, the examining bodies and their personnel confirm in the application and personnel forms that they have read and understood the requirements set out in this guidance and undertake to comply with them.

This guidance is intended to provide examining bodies and their personnel with clear guidelines to refer to (see section 2). In addition, this guidance also describes the FOPH's regular reviews of the current state of knowledge and technology as well as selective inspections of the examining bodies (section 3).

The conditions for submitting applications are set out in the *Guidance for applications to become an examining body for certificates of competence for treatments using non-ionising radiation and sound in accordance with the Ordinance to the Federal Act on Protection against the Risks associated with Non-lonising Radiation and with Sound (O-NIRSA)*.

2 Tasks and obligations of the examining body

This section describes the tasks and obligations of the examining body. Table 1 provides an overview.

Table 1. Overview of tasks and obligations of the examining body (gi = guidance).

Tasks/obligations	Instance compétente	Section gi
General requirements	Examining body	2.1
Administrative tasks	Examination office	2.2
Organisation and conduct of the training and of the exam	Examining body and/or teachers and experts	2.3
Training and examination procedures	Examining body	2.4
Admission requirements for training and examinations	Examining body	2.5
Verification of appeals	Examination board	2.6
Compliance with advertising requirements	Examining body	27
Issuing and notification of certificates of competence	Examining body / Examination office	2.8.1-2.8.3
Removal of individuals from the ePortal NIRSA following revocation of certificates of competence	Examining body	2.9
Conducting of training and exam evaluations	Examining body	2.10
Annual reporting of examination statistics	Examining body	2.11
Notification and submission of changes	Examining body	2.12.1-2.12.4

2.1 General requirements

Data protection

The Federal Act on Data Protection (Data Protection Act, FADP; SR 235.1) aims to protect the privacy and fundamental rights of individuals by ensuring the protection of their data. According to this law, data must be processed correctly and proportionately, and protected against unauthorised access and misuse.

In this context, it should be noted that the personnel of the examining bodies may not disclose any data relating to persons who acquired a certificate of competence or individuals who have attended or wish to attend their courses to third parties.

Professional confidentiality

The personnel of the examining bodies is also subject to professional confidentiality in accordance with art. 321 of the Swiss Criminal Code (SR 311.0).

Publication of prices

In accordance with art. 10 para. 1 let. d. and m. of the <u>Ordinance on Price Indication (Price Indication Ordinance, PIO; SR 942.211)</u>, the examining bodies are obliged to inform persons interested in acquiring a certificate of competence of the cost of their courses. The examining bodies therefore inform the public about the prices of their services (courses) via their website or by other means.

2.2 Administrative tasks

Each examining body runs an examination office to take care of the administrative tasks associated with the modules and examinations. The examination office also serves as a point of contact for any related queries.

2.3 Organization and conduct of the training and the examination

The examining bodies conduct both the training and the examination. They ensure that the relevant training and examination requirements are met in accordance with the training programmes and examination content of the administrative body, as specified in the module descriptions.

In addition, the examination experts fulfill the following tasks and obligations:

- prepare examinations tasks and rubrics;
- conduct the examinations in accordance with the rules stipulated in the examination regulations;
- record the examination results in writing in the specified documents or examination rubrics;
- participate in further training courses for examination exports organised by the examining body annually;
- participate in examination conferences (preparatory meetings, debriefings, etc.);
- undertake to maintain secrecy about the examination process and content.

2.4 Training and examination procedures

A detailed description of the training and examination procedures can be found in the examination regulations of the administrative body. The examining body must comply with these registration and examination procedures. The following points are covered:

- Announcement of the modules and module examinations
- Training and examination registration
- Costs
- Withdrawal
- Non-admission and exclusion
- Assessment of the examination
- Appeal
- Resits

2.5 Admission requirements for training and examinations

For each module, the examining body must check whether candidates meet all the requirements to participate. These requirements are set out in the examination regulations of the administrative body.

2.6 Verification of appeals

Each examining body has an examination board. This board must comprise at least four persons and no more than five members. These members have the same qualifications as the examination experts (see section 4.1 of the *Guidance for applications to become an examining body for certificates of competence for treatments using non-ionising radiation and sound in accordance with the Ordinance to the Federal Act on Protection against the Risks associated with Non-Ionising Radiation and with Sound (O-NIRSA))*. The examination board considers appeals in the first instance. When performing this role, the board may request a non-binding opinion from the FOPH. Upon receiving such a request, the FOPH may issue a general and non-binding opinion for the attention of the examination board. However, the FOPH is not competent to deal with individual cases. The examination board ultimately decides on the appeal.

2.7 Compliance with advertising requirements

When advertising training and examinations for certificates of competence, it must be <u>clearly stated</u> <u>and apparent</u> which examining body will issue the certificate of competence. External providers are not considered to be examining bodies. Examining bodies may only advertise using the name with which they are listed in the FDHA O.

This applies to the following areas, among others (non-exhaustive list):

- Online listings (on every subpage)
- · Advertising letters
- Advertising emails
- Promotional calls
- ...

Advertising for the acquisition of certificates of competence may only be carried out if the relevant examining body for the certificate of competence is included in the FDHA O Annex. The relevant date for this listing is the date on which the revised FDHA O list is published in the Official Compilation of Federal Legislation. Examining bodies whose certificates of competence are added to the FDHA O list are notified of this date by the FOPH accordingly.

2.8 Issuing and notification of certificates of competence

2.8.1 General

A certificate of competence must be acquired in full from a single examining body. This means that it is not possible, for example, to complete a technologies module with one examining body and the other modules with a different examining body. However, for any additional certificates of competence, a TKS module can be completed with a different examining body, which will then issue the new certificate of competence.

2.8.2 Issuing of certificates of competence

The examining body issues a certificate of competence to individuals who have passed all the examinations and completed the two compulsory practical treatments with running equipment as part of the TKS module. The certificate of competence must include the following information:

- a) Designation of the certificate of competence in accordance with Number 1 of the Annex to the FDHA O
- b) First name and last name of the person who has obtained the certificate of competence
- c) Date of birth of the person who has obtained the certificate of competence
- d) Approved treatment in accordance with Number 1 of the Annex to the FDHA O
- e) Name of the examining body in accordance with Number 1 of the Annex to the FDHA O
- f) Date and place of completion
- → No further information should be included on the certificate of competence. Please note that the individual modules that make up a certificate of competence are simply a structuring format for the training required by an examining body, however they have no legal validity in the FDHA O. For this reason, the certificate of competence does not include details of completed modules.

Important: Prior to issuing a certificate of competence for the first time, the draft must be presented to the FOPH who must give their consent to issue the certificate of competence in this form.

We recommend the following text for certificates of competence:

"First name, last name, date of birth dd.mm.yyyy, successfully completed the examinations required for certificate of competence xy by examining body x, as per the requirements for the certificate of

competence based on the Ordinance to the Federal Act on Protection against the Risks associated with Non-Ionising Radiation and with Sound (O-NIRSA) of 27 February 2019.

Examining body x is listed as an examining body by the Federal Department of Home Affairs for the issue of certificates of competence conforming to O-NIRSA."

→ It is also advisable to mention the ePortal, ideally with a QR code to the web page:



Link to NIRSA ePortal

Falsification or forgery of certificates of competences

The falsification or forgery of certificates of competence is prohibited and punishable by law. According to art. 252 (<u>Forgery of certificates</u>) of the <u>Swiss criminal code (SR 311.0)</u>, any person who with the intention of furthering their own position or another's position, forges or falsifies identity documents, references, or certificates; uses such a document in order to deceive another;, or uses a genuine document of this nature that does not apply to them in order to deceive another, shall be liable to a custodial sentence of no more than three years or a monetary penalty.

2.8.3 Notification of persons with certificates of competence in the ePortal NIRSA

After being entered in the FDHA O, examining bodies receive access to the NIRSA ePortal where they can provide notification of persons who have obtained certificates of competence. In this way, they must notify the FOPH of individuals with a newly acquired certificate of competence within one month of it being obtained. The examining bodies are responsible for ensuring that the data is up to date and correct. Link to the portal: NIRSA (admin.ch).

2.9 Removal of persons from the ePortal NIRSA following the revocation of certificates of competence

Criteria for revoking certificates of competence

The cantons may revoke certificates of competence in the event of repeated violations by the competent person that could have serious consequence (art. 9, para. 4, NIRSA).

A certificate of competence may be revoked, if the legal provisions are not complied with, treatments are not carried out in accordance with the current state of knowledge and technology, and/or present a high potential risk.

Procedure for revoking the certificate of competence

- The certificate of competence is withdrawn by the competent cantonal enforcement authorities.
- The cantonal authorities are directly authorised to revoke the certificate of competence from its holder directly. A copy of the decision is sent to the examining body that has issued the certificate and to the FOPH.

Role of the examining body in the event of revocation of the certificate of competence

Upon receiving the canton's decision, the examining body removes the person in question from the list of certificate holders in the NIRSA ePortal and informs the FOPH and the competent canton.

2.10 Evaluation of training courses and examinations

The examining bodies must regularly evaluate the training and examinations. Once the training has been completed and the examination passed, participants are asked to complete a standardised questionnaire. The examining bodies record and evaluate the results in writing. Based on this feedback, they regularly review and adapt the course planning (schedule and content), internal and external processes, teaching methods, and all training materials as necessary. They document all these steps.

The FOPH provides the examining bodies with a standardised questionnaire to carry out the evaluation. This questionnaire covers the following points:

- overall customer satisfaction:
- communication and organisation of the examining body;
- content of the training and its relevance to practice;
- skills of the trainers;
- conduct of the examination and the skills of the examination experts;
- teaching methods and techniques used.

2.11 Annual reporting of examination statistics

Every year, all organisations responsible for examinations must report to the FOPH the total number of passes and failures for each module. These statistics must cover the period between October of the previous year and September of the current year.

By the end of September of each year, the FOPH sends the form to be completed to the examining bodies.

This report must be completed and returned by the 31st of October via sn-nissg@bag.admin.ch.

2.12 Notification and submission of changes

2.12.1 Changes in personnel

Changes in trainers, examination experts and members of the examination board must be submitted to the FOPH in advance. To do so, the most recent personnel list must be modified by entering the changes and highlighting them in green. Contact sn-nissg@bag.admin.ch to request a link for a secure file transfer and upload of this list, together with the personnel form, work experience confirmations and diplomas of any new personnel who are to teach further modules, to the Confederation's file transfer service. For data protection reasons, sensitive data such as dates of birth cannot be sent by email.

2.12.2 Changes in the content of teaching materials, teaching plans, examination questions, etc.

If any non-substantial part of a certificate of competence from an examining body listed in the FDHA O changes, the examining body is required to notify the FOPH of this change <u>within three months</u> (see next section about substantial changes). To do so, a change form must be requested via <u>snnissg@bag.admin.ch</u> and submitted together with all the related documentation. Please note that the FOPH may perform selective checks of content-related and organisational aspects of the examining body at any time (see also section 3.2 and 3.3). If changes have been made without notifying the FOPH within the stipulated period, the examining body may be removed from the list.

The obligation to report changes applies to all content-related and organisational changes that no longer correspond to the information provided in the application submitted to the FOPH. These include, among others, the following changes:

- Deviations in the training programmes, examination content and examination rubrics
- Newly added laser protection courses recognised by the examining body

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<u>Exceptions</u>: the personnel list and new examination questions. Notification of these changes can be submitted without the change form.

2.12.3 Substantial changes in content

If the content of a certificate of competence listed in the FDHA O changes substantially, all relevant documentation (application forms, training content, examination questions, personnel, etc.) must be submitted in advance to allow the FOPH to review the proposed changes. These changes can be submitted at one of the official deadlines.

This includes changes to the following:

- Newly structured modules
- · Completely new teaching materials or significant parts thereof
- Entirely new teaching plan structure
- Switching to online teaching for certain modules (only possible for modules on fundamentals and modules on technologies).

2.12.4 Change of name of the examining body

If the examining body changes its name, this information must be communicated to the FOPH. This must be accompanied by an excerpt from the commercial register stating the new name.

The FOPH asks the FDHA to change the name in the O-FDHA and adapts of the examining body name in the NIRSA ePortal.

The examining body must inform all individuals who have obtained a certificate of competence from them of this change. It must also offer to issue a certificate of competence in its new name to those people who wish to receive one.

3 Periodic reviews by the FOPH

3.1 Current state of knowledge and technology five-year review

At least once every five years, the FOPH verifies that the documents submitted by the examining body are still in line with the current state of knowledge and technology as set out in the training programmes, examination content and examination regulations of the administrative body. If the administrative body has made any amendments, the guidance will be adjusted accordingly, and all examining bodies on the FDHA O list will be contacted and asked to update their training programmes, examination content and examination regulations within the specified deadline. They will also be asked to submit an amended application. This must be carried out in accordance with the current rules set out in the guidance.

As part of the five-year review, the FOPH will check in particular that:

- a. all documents correspond to the current state of knowledge and technology;
- b. all significant changes to the documents have been reported in a timely manner;
- c. the personnel employed for training and examinations have the required qualifications;
- d. evaluations of training and examinations are carried out regularly (see section 2.11).

If the FOPH finds that an examining body is not fulfilling these duties, it will require the body to comply within three months. If the examining body fails to do so by the end of the deadline, the FDHA may remove the examining body from the annex.

3.2 Case-by-case review

The FOPH may also conduct case-by-case reviews to determine whether the examining bodies listed in the FDHA O are acting in compliance with the organisational and content-related aspects of their documents. For example, the FOPH may request all completed examination sheets, including the assessment and assessment scheme of the most recent examination conducted by the examining body. On this basis, it can then determine whether the examination questions and assessments are appropriate. If, for instance, changes have been made to the original application without notifying the FOPH in advance (personnel) or within three months (changes to other parts of the application), the examining body may be removed from the list (see also section 2.13.2).

The FOPH also regularly checks the websites of the examining bodies. Should such checks reveal that an examining body is not complying with the requirements of the NIRSA or the O-NIRSA or is failing to adhere to the training and examining documents it submitted and its corresponding scope of competence, the body can be removed from the FDHA O.

3.3 On-site inspections

The FOPH reserves the right to carry out unannounced inspections. In accordance with Art. 27, para. 2 of the O-NIRSA, the FOPH must be provided with all necessary information and documents free of charge. Additionally, the FOPH must be granted access to premises.