IASIOS

INTERNATIONAL ACCREDITATION SYSTEM FOR
INTERVENTIONAL ONCOLOGY SERVICES

IASIOS Accreditation

Application Manual

Guide to the IASIOS application process
for becoming an Accredited Centre

CIRSE

www.iasios.org

For your convenience, this application manual has been translated into multiple languages. Visit the IASIOS page to see the array of translations we have available.

If you would like a copy of our application manual in one of our available languages, please contact the IASIOS office.

Contents

INTRODUCTION

The International Accreditation System for Interventional Oncology Services (IASIOS) has been specifically developed for medical facilities operating in interventional oncology (IO) and aspiring for formal recognition of their IO service line as part of an existing institution or as an independent entity. The CIRSE Standards of Quality Assurance for Interventional Oncology establish the highest standards for patient care and treatment, as well as the safety and efficiency of interventional procedures involved in the management of cancer patients.

IASIOS aims to provide guidelines for setting standards in IO, to support IO facilities in their journey to meeting the standards and to recognise their efforts with official accreditation approval. This Application Manual provides a step-by-step guide through the IASIOS application process.

The Standards provide a framework for the gold standard of IO services and something we hope that all facilities will strive to achieve over the coming years as IO becomes a firmly established clinical service. Some of the standards are what we refer to as core requirements and must all be met for a facility to become an Accredited Centre. We refer to other standards as extended requirements and include standards required for a facility to be awarded Centre of Excellence.

The CIRSE Standards of Quality Assurance are marked with an IASIOS seal to represent the core criteria that are required for Accreditation. Please refer to the Supporting Evidence Checklist (Appendix 3) to get a clear overview of which criteria will be evaluated for your facility to become IASIOS accredited.

As part of the application, hospitals must complete an Internal Case Review. This is an opportunity for hospitals to assess and demonstrate the status quo of data capture for internal cases. This is not an on-site audit. Hospitals are asked to select 30 random cases from the last 12 months and use this data for questions 13, 30 and 36, where you are asked to fill in details into an Internal Case Review (Appendix 2). Please see section 2.3 in this document for more detailed instructions.

While hospitals are recommended to complete their application within 12 months, there is no time limit or deadline to have completed the application process. The aim of IASIOS is not to evaluate the status of your facility against the standards at the time of registration but rather to support you as an Enrolled Centre while you are improving your IO services and assessing your status after you have made any necessary changes to policies or procedures and are ready to have that achievement officially recognised and accredited.

1. WHAT TO EXPECT

1.1 Enrolling

After getting authorisation from your administration or head of department, fill out the online registration form. You will be asked to appoint an authorised representative, deputy authorised representative and a main account holder. The authorised/deputy representative can also be the main account holder. We highly recommend assigning the roles within your team according to their involvement with the application.

The **authorised representative** is appointed with the formal responsibility of the application and the accuracy of the information provided. They are the only person who will be able to submit the final application online. They will also be able to view invoices in the myIASIOS portal. The authorised representative may be a senior staff member from the clinical, technical or managerial staff. It is important that they are in a position of sufficient authority to ensure that access to all necessary records, documents and systems is available to IASIOS in case of an on-site audit.
The **deputy authorised representative** will be able to work on the application and view invoices, but cannot make changes to the facility information, nor submit the final application.

The **main account holder** will be responsible for maintaining correspondence with the IASIOS team. They will be able to make changes to the application and facility information in the myIASIOS portal. They cannot submit the final application.
Following your registration, you will receive a confirmation email that includes a facility code that will be required for new users to be able to join your facility, please be aware that every user must activate their account through their confirmation email to be able to access the MyIASIOS for the first time.

After you have registered, you will receive an invoice for the enrolment fee and annual administration fee (if applicable), accessible through the "Invoices" tab on your myIASIOS area (Appendix 1). Once payment has been processed, you will be granted the status of IASIOS Enrolled Centre. You will receive the respective logos and access to the online IASIOS application and internal case review through your myIASIOS login.

1.2 Preparing the application

We recommend having several members from your hospital working on the application together and that you consult with your facility's Quality Assurance department. In our experience, they have been a valuable resource to the centres that have achieved accreditation.

Please start with reading through the Standards of Quality Assurance document and familiarising yourself with the requirements. Please note that IASIOS splits the requirements

and supporting evidence in the Standards of QA into "core criteria" and "extended criteria". In the online application, you will see which questions are core criteria required to receive accreditation. You will also be required to do an internal case review on 30 randomly selected patient files to complete the application.

It is unnecessary to provide all the supporting evidence documents when you submit your application form, but please have them ready for submission if the assessors request supplemental information. Facilities may request additional consultation at any stage in the application cycle for an additional fee as stipulated in the Terms and Conditions.

Please note that there is no deadline for the application submission, and the IASIOS team is available to consult you on technical and administrative issues along the way.

1.3 Assessment

After your application and internal case review have been submitted, they will be reviewed by two independent assessors. If the assessors find the descriptions and supporting evidence unclear or ambiguous during the evaluation process, they will request additional clarification or documentation from the facility. If the responses from the facility are still not enough for the assessors to accept the criteria as being met, a remote audit in the form of a teleconference will be scheduled. In rare cases, if the remote audit was unsatisfactory, a Corrective Action Plan (CAP; Appendix 5) is required from the facility with a description of the criteria that have not been met and what improvements will be implemented to correct them and possibly an on-site audit. The centre remains an IASIOS Enrolled Centre until a satisfactory assessment is achieved.

Once the process has been concluded, you will receive a letter from the IASIOS team informing you of the evaluation results, your IASIOS Accredited Centre seals and your framed IASIOS Accredited Centre Certificate.

If you have any questions about the accreditation process, please don't hesitate to contact the IASIOS team.

2. THE APPLICATION PROCESS

2.1 Step-by-Step Overview for Enrolled Centres

Get started:

Step 1: Read through and familiarise yourself with the Standards of Quality Assurance in Interventional Oncology.

Step 2: Log in to your online myIASIOS area, read the Application Manual, and go through the questions on the application form.

Evaluate and Plan:

Step 3: Recruit team members to work on the application with you (tip: we highly recommend you ask someone from your facility's Quality Assurance department – they likely have many of the answers already!)

Step 4: Evaluate your facility's current standing regarding each core requirement.

Process:

Step 5: Update policies and procedures as necessary

Step 6: Implement improvements where needed

Re-evaluate:

Step 7: Assess your suitability for accreditation

Step 8: Fill out the online application and conduct the internal case review. Go through the checklist of supporting evidence and ensure that your facility would be able to provide all documentation upon request.

Submit:

Step 9: Submit your completed application through your myIASIOS area

Step 10: Receive feedback or questions from the Assessors, providing additional clarification or evidence where necessary.

Celebrate your status as an Accredited Centre!

2.2 Filling in the Application Form

Please start filling in the IASIOS Application in your myIASIOS portal as you work through the core criteria for accreditation. You can save your progress and as you go and the questions do not have to be answered in order. The Application Form is a comprehensive assessment tool based on the 13 sections outlined in the Standards of QA in IO that will demonstrate to what degree an IO facility meets the standards.

Each of the 52 questions has a Yes/No answer, with specific questions asking you to elaborate on the answer. Each question is aligned with a "required evidence" (supporting evidence) point listed in the Standards. We recommend that each question be read alongside the corresponding criteria described in the Standards for further clarification. Following each question is a text box where you can list what evidence you have available for the assessors, should they choose to evaluate it in further detail. Please see Appendix 2 for detailed instructions on using the online application portal.

The application specifies whether each question is a **core** or an **extended** requirement. Each of the 28 core requirements is mandatory to achieve the status of IASIOS Accredited Centre. In comparison, the 24 extended requirements are considered evidence of the highest level of IO care and are necessary to achieve the status of IASIOS Centre of Excellence.

Core requirements – mandatory requirements necessary to achieve IASIOS accreditation and the status of IASIOS Accredited Centre (28)

Extended requirements – additional requirements necessary to achieve the status of IASIOS Centre of Excellence (24)

Answers to questions about extended requirements will not be considered in the evaluation for IASIOS Accredited Centre. However, attempting all the questions may help facilities improve the quality of their IO service line, patient safety and patient satisfaction. Answering questions from extended requirements cannot compensate for unanswered core questions. A facility can apply to be considered a Centre of Excellence after being an Accredited Centre for the entire four-year accreditation period and has decided to apply for re-certification.

The core requirements correspond to the following standards:

Section 1: a, c, e, f, g	Section 6: a, b, c, d	Section 11: a
Section 2: b	Section 7: a, b	Section 12: a, b
Section 3: a, c	Section 8: a, b, c, d, e	Section 13: none
Section 4: b, c, d	Section 9: none	
Section 5: d	Section 10: c	

2.3 The Internal Case Review Form

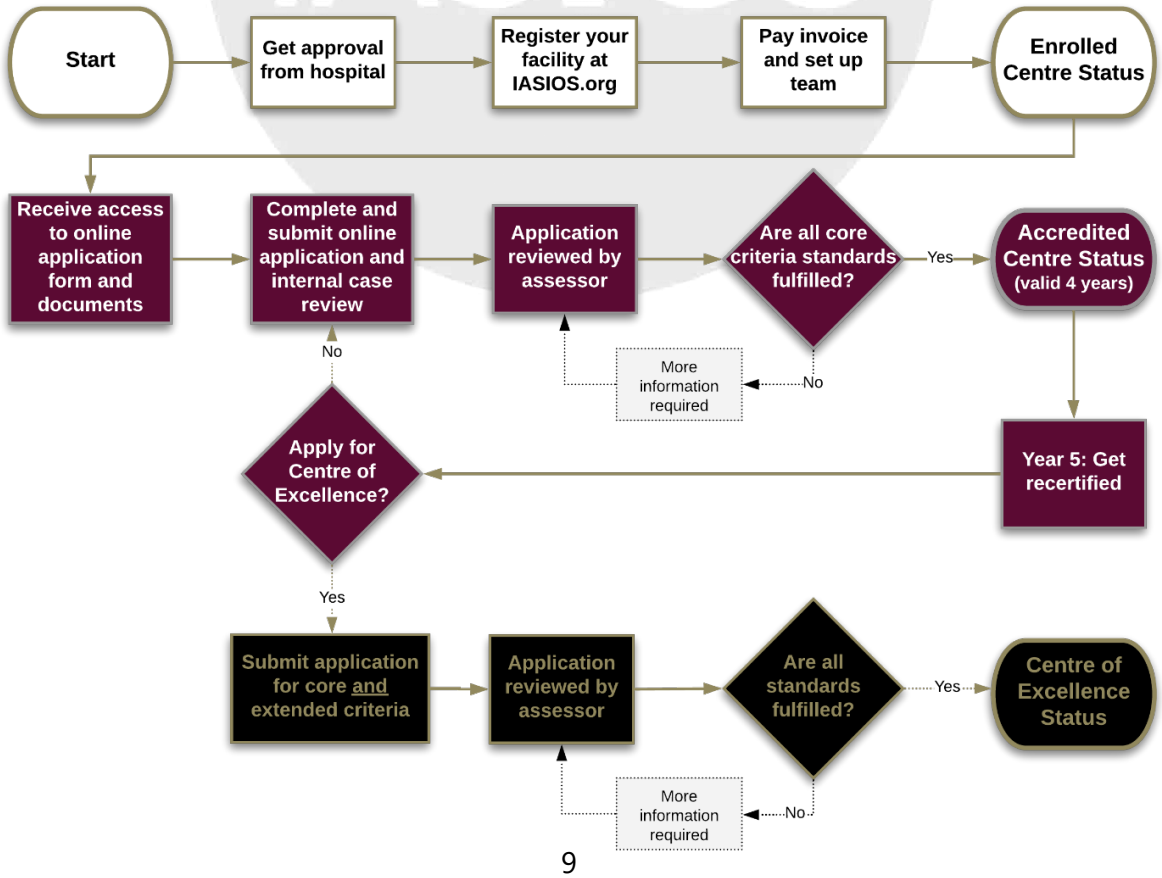
For evidence requirements 3c, 7b and 8d, you are asked to review 30 randomly selected patient cases from 12 months prior to application submission and use their information to complete the Internal Case Review (see Appendix 2). You must keep a record of the **patient identifier numbers** for the cases used in the event of an external audit at a later date.

For requirement 3c, please check each patient file to see if they include all of the information listed in the Minimum Dataset Checklist (Appendix 4) regarding the management of patient records. Please use the same patient files to check if the requirements for 7b regarding patient consent and the requirements for 8d regarding patient care during treatment were met. Please fill in the Internal Case Review with information from all 30 cases.

If there is missing information in the Internal Case Review, please provide an explanation and a description of what measures will be implemented to correct for this in the future in the corresponding section provided in the Application for questions 13, 30 and 36.

2.4 Submitting the Application

When you are positive that your application is complete and meets all core requirements, your facility's authorised representative should submit the Application Form. You will not be able to make any changes to the application after it has been submitted. Please ensure that all supporting evidence for the core requirements is readily available to you, should you be requested to submit them as well.



3. ASSESSMENT AND EVALUATION

3.1 The Assessment Process

After the complete application has been made available to the Assessors, including any potential supplemental documents requested, it will take approximately 8-12 weeks to receive the decision regarding your accreditation. Below are the steps involved in the assessment process.

1. Application submitted online
2. Assessors review the application, evaluate the supporting evidence and request additional evidence if necessary
3. Facility gets an email notification if additional evidence or information is required
4. Facility submits additional information within two weeks (if required)
5. If additional information was not satisfactory, a remote audit via video conference may be requested
6. Assessors fill out the evaluation and make a recommendation on whether to grant accreditation
7. IASIOS Chairperson signs off and approves the Assessors' decision
8. If accreditation is not granted after two rounds of evaluations and a remote audit, the facility will receive either a deferred or a denied status
9. If accreditation is granted, the facility receives status and seal accordingly, and the hospital status on the IASIOS website is updated

3.2 Remote audits

Remote audits will be conducted in cases where clarification is needed from the information provided in the application form that was not sufficiently supplied during the first two rounds of assessment. The facility will get the chance to address all open issues from the feedback they have already received from the assessors through a presentation via video conference.

3.3 Assessment outcomes

The accreditation decision has three possible outcomes: Approved, Deferred or Denied. If the accreditation is Deferred, the facility will receive a detailed report outlining what is required to achieve Accredited Centre Status. The facility has 90 days to submit a proposal with a detailed improvement and implementation strategy or a Corrective Action Plan (CAP; Appendix 5), with the option of requesting a consultation. Upon submission, assessors may request evidence of the implementation. If accreditation is denied, the facility has 90 days to submit a proposal or CAP, with the option of requesting a consultation and must also schedule an on-site audit. In both cases, the IO Facility maintains its Enrolled Centre status until Accredited Centre status is approved.

4. ASSISTANCE AND SUPPORT

Administrative Support

The IASIOS team can be contacted at any time through the messaging system on your myIASIOS area, via phone Monday-Thursday from 9:00-17:00 CET and Fridays from 9:00-15:30 CET at +43 1 904 2003 57 or via email at office@iasios.org.

Please do not hesitate to contact us if you have any questions regarding the application process, requirements or supporting evidence. The IASIOS team may contact you periodically throughout your enrolment phase to request status updates and/or teleconferences to clarify any questions you may have.

Website

On our website www.iasios.org you can find helpful information regarding the IASIOS system and accreditation process. You can read general information about the background and committee members for IASIOS, download the Standards of Quality Assurance document, look up details about the accreditation pathway and see what hospitals are currently enrolled and accredited, to name a few.

Appendix 1 – Using the myIASIOS Platform

1.1 Updating your facility information

Once the facility is registered, the authorised representative or main contact person will be able to edit the facility information by clicking on 'My Profile 'and filling in the new data. To save changes after adding the new information, please do not forget to click on 'Update Facility Profile'.

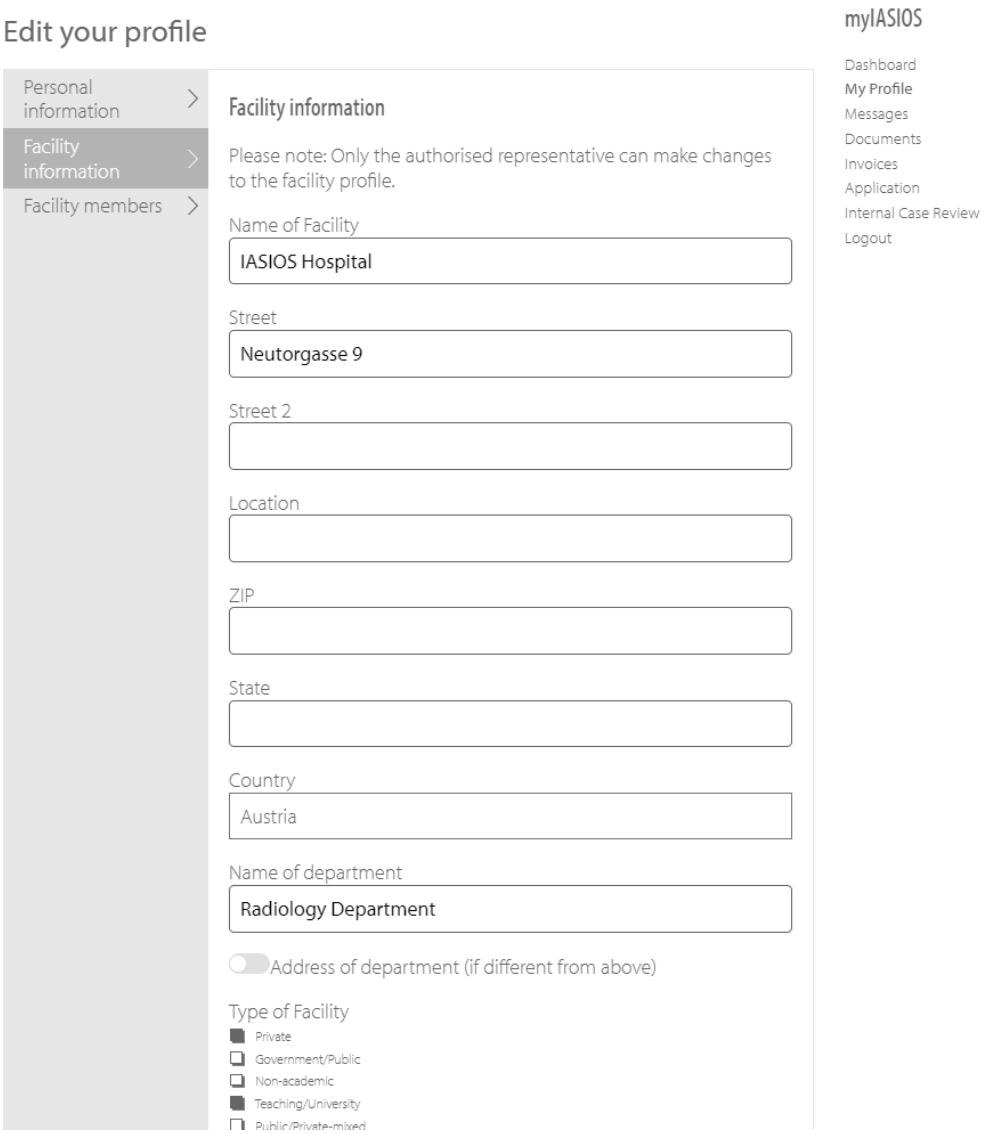


Figure 1: Updating Facility Information

1.2 Adding people from the facility

To help manage your application, additional people can join your facility application. Once registered, you will receive an email with a facility registration code that you can pass on to the rest of your team. Please note that all user accounts need to be activated through the "Activate account" button in the confirmation emails before they can be used.

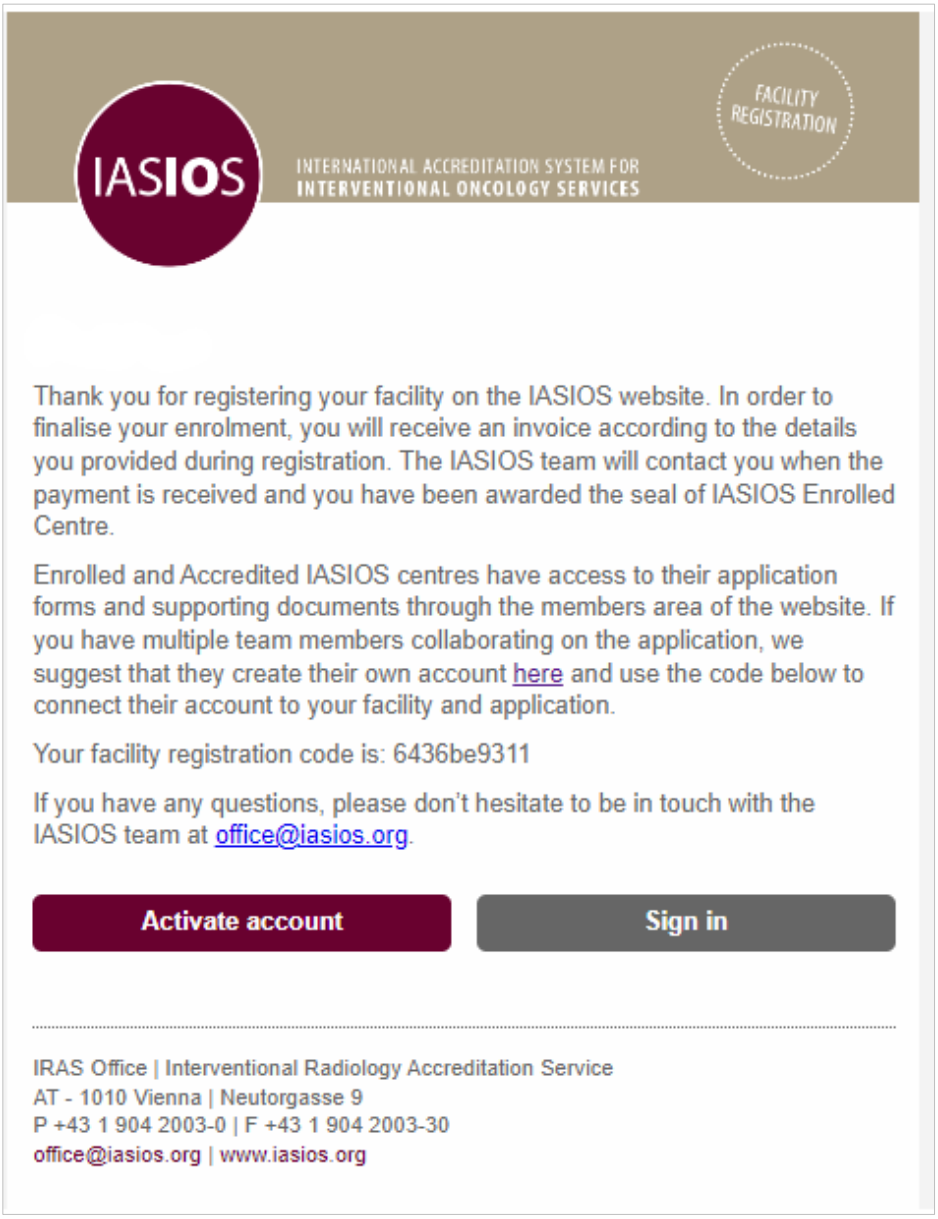


Figure 2: User activation email

Additional users can register through the website at www.iasios.org/user-registration/ They will need to fill out the Facility Code sent to the main account holder when registering the facility in order to be linked to the shared application.

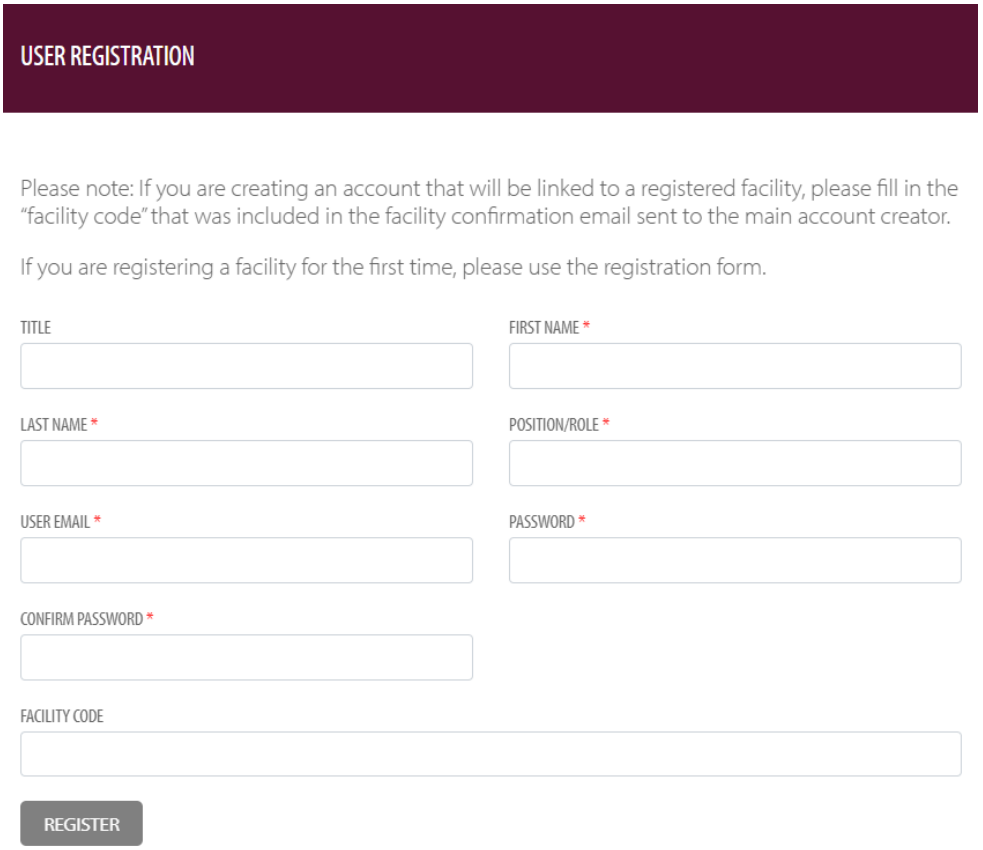


Figure 3: User registration form

1.3 Invoices

Facilities will have access to their invoices on the myIASIOS portal. To open your invoices, go to 'Invoices' and click on the grey bar, and you will have access to your invoices in PDF format, ready to download or print. Please note that only the Authorised Representative, Main Contact Person or Deputy Authorised Representative will be able to view the invoices.

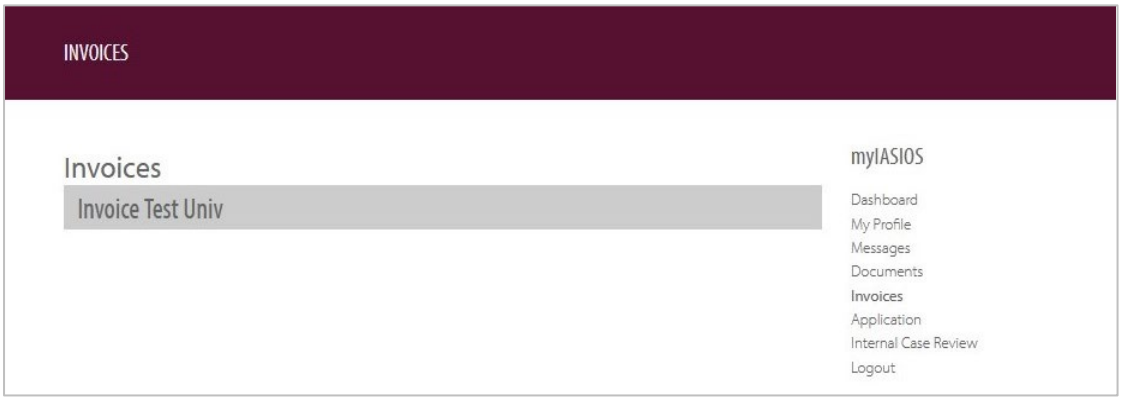


Figure 4: Invoices in myIASIOS

Appendix 2 – Filling in the Application

Notes on submitting the application:

- Only the authorised representative can submit the completed application
- Text boxes for descriptions, explanations and lists of evidence must be filled in for the question to be considered complete
- To avoid data loss, please click the 'Save' button as you progress throughout the application.

In the application form, each Standard 1-13 is labelled at the top and bottom to move efficiently between the section you are working on. Anyone registered at your facility can work on answering the application. Each question is labelled whether it corresponds to a Core or an Extended criterion.

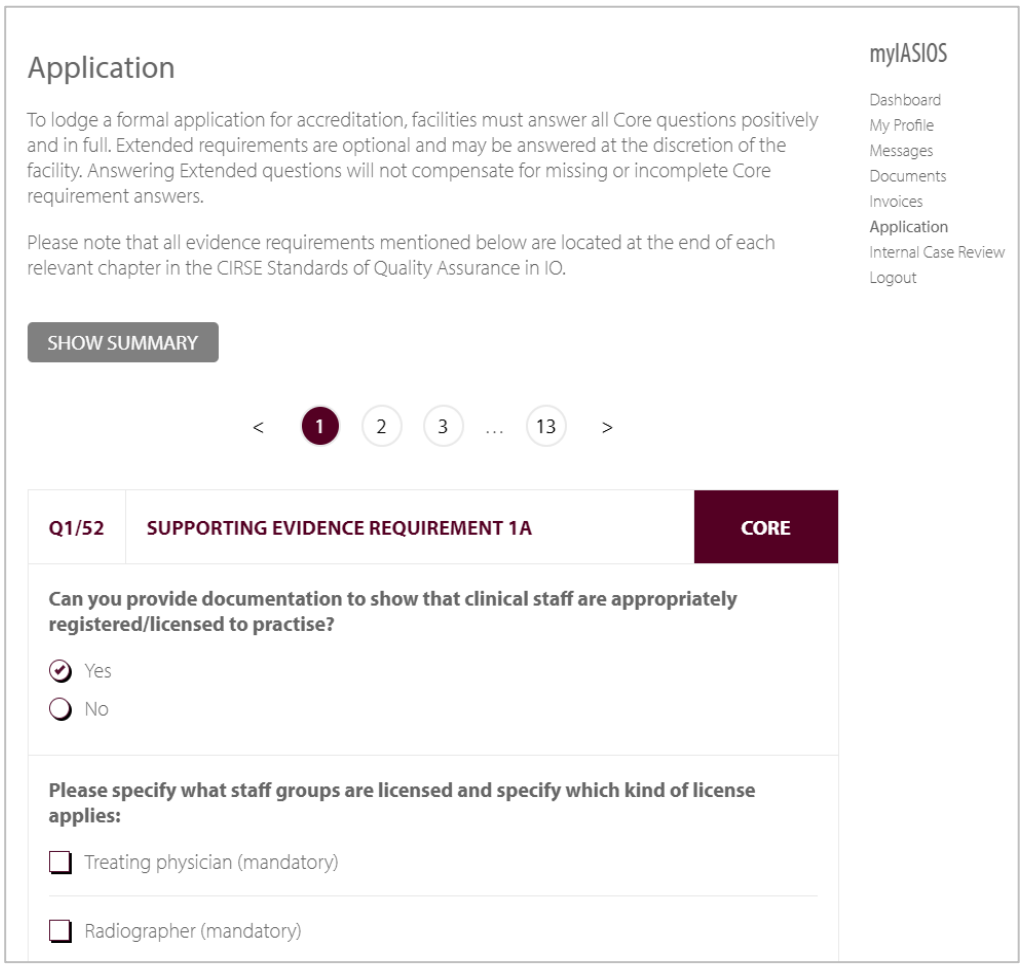


Figure 5: Application form

For each question, text boxes are asking for a list of evidence you have available. Please describe how you can demonstrate your compliance with each criterion and ensure that you have these documents available to you should the Assessor request to see them. Some questions will ask for a description or explanation of your answer. Text boxes in Core criteria questions must be filled in for the question to be considered complete in the system.

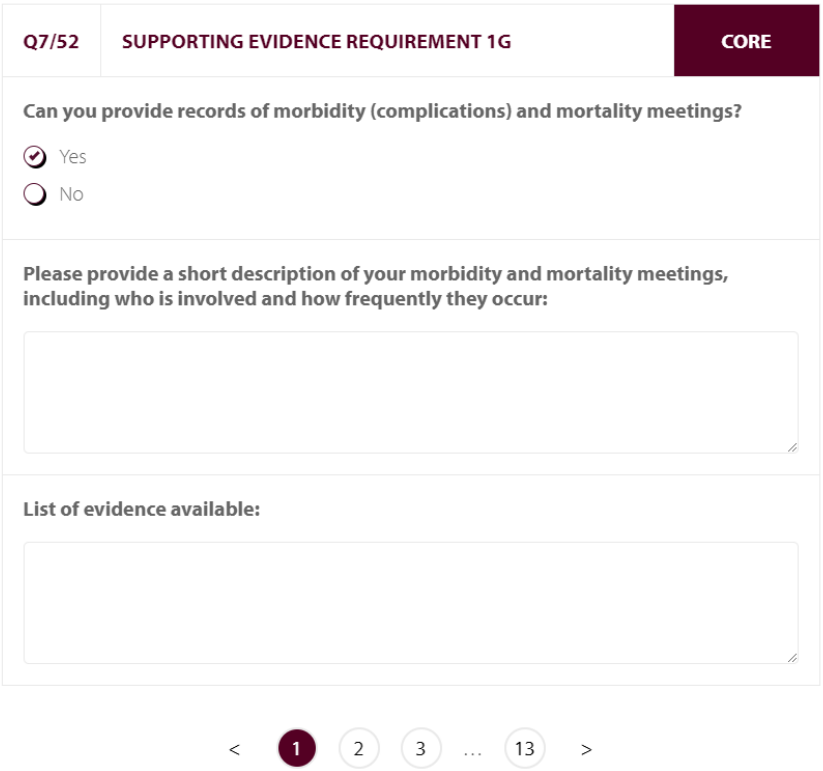


Figure 6: Filling out core criteria questions

Each of the 28 core criteria questions are tracked automatically when completed to track your progress. You can also click "show summary" to see a list of which questions still require more information.

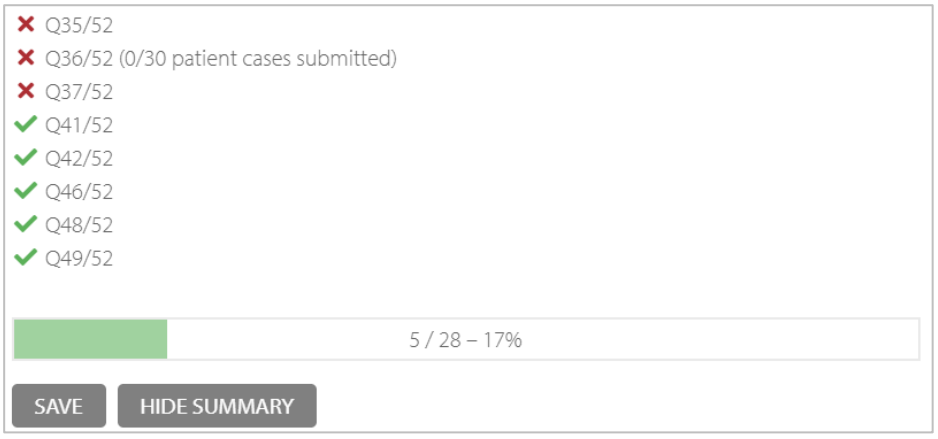


Figure 7: Use the application summary to keep track of unanswered questions

2.1 The Internal Case Review

The Internal Case Review encompasses different Standards and is therefore referred to in 3 separate questions. Please use the same 30 patients selected randomly from the last 12 months for all three questions. A separate summary for the internal case review keeps track of your progress.

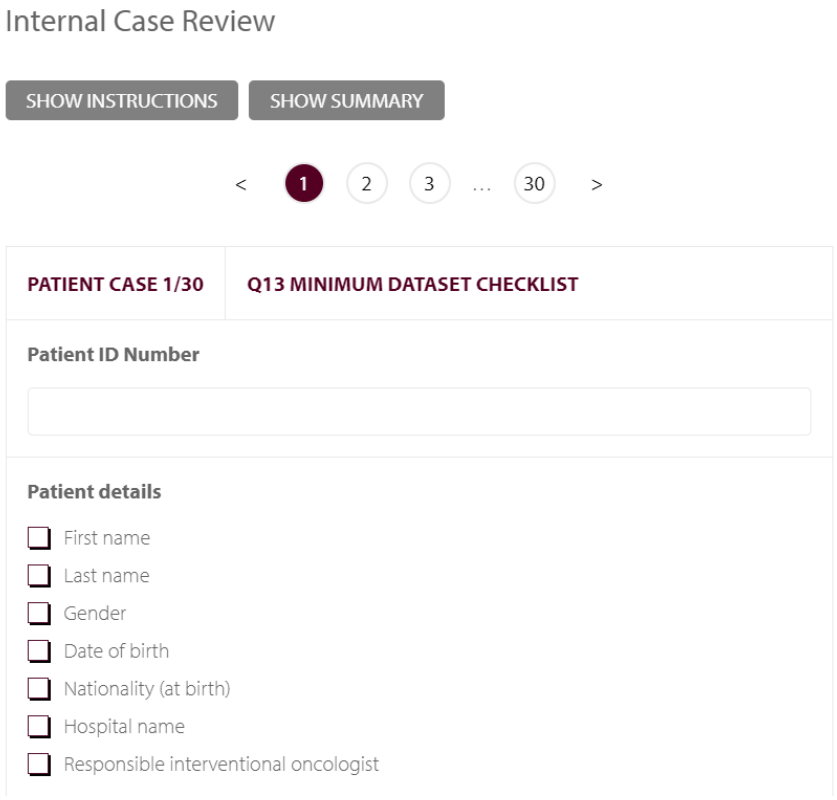


Figure 8: Internal Case Overview

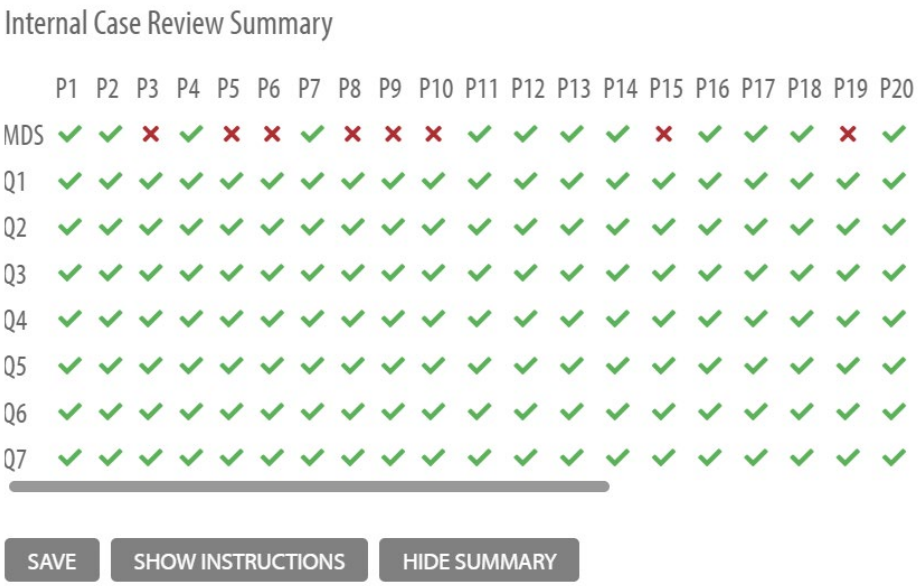


Figure 9: Monitor your progress by clicking 'Show Summary'

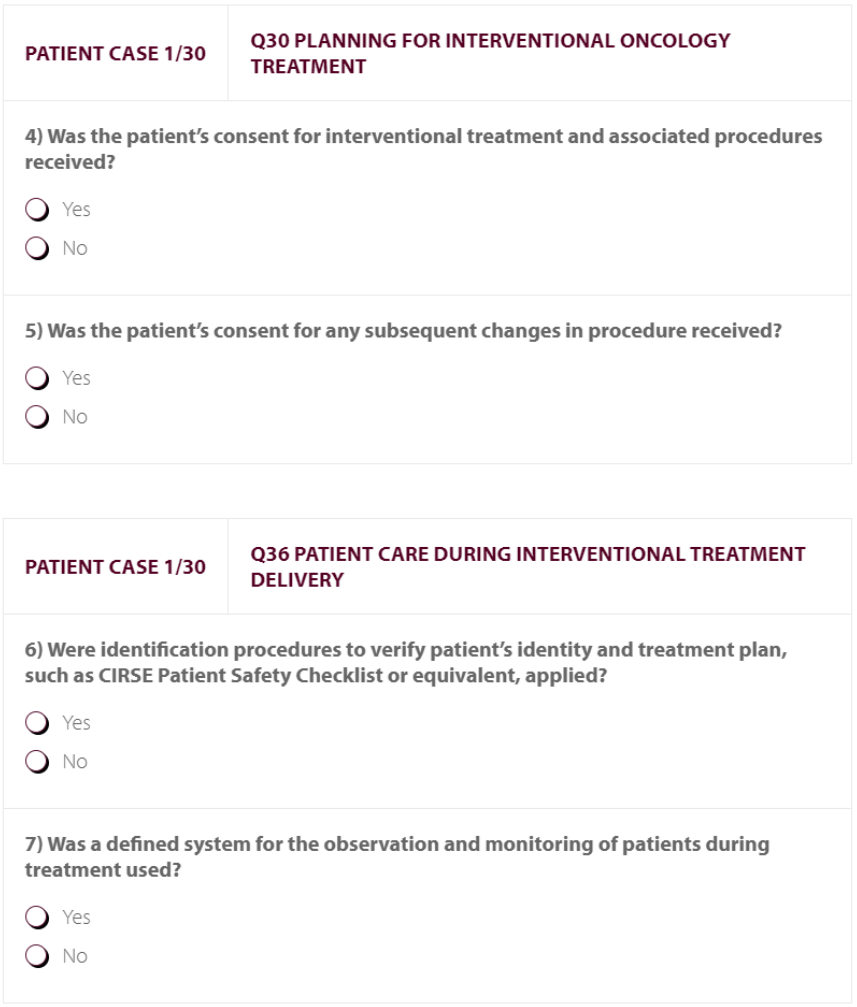


Figure 10: Example of questions from the Internal Case Review application

When all questions have been completed, and the progress bar at the bottom of the page is 100%, the Authorised Representative will see the option to submit the application.

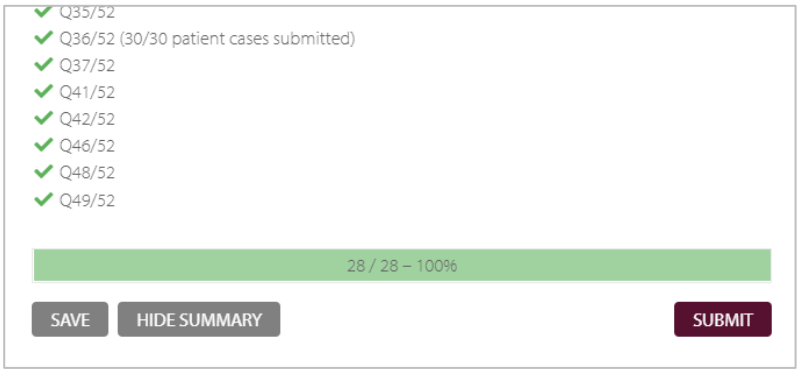


Figure 11: A completed application

2.2 Assessment

Once the assessors have evaluated your facility, you will receive an email confirming your accreditation or requesting more evidence and information that you will need to submit within **two weeks**.

On the platform, when you reopen the application, you can read and reply to the assessors' comments (See Figure 14). If you need to upload documents with supporting evidence, please use the comments text box to link to a folder in your Cloud (See Appendix 2.3).

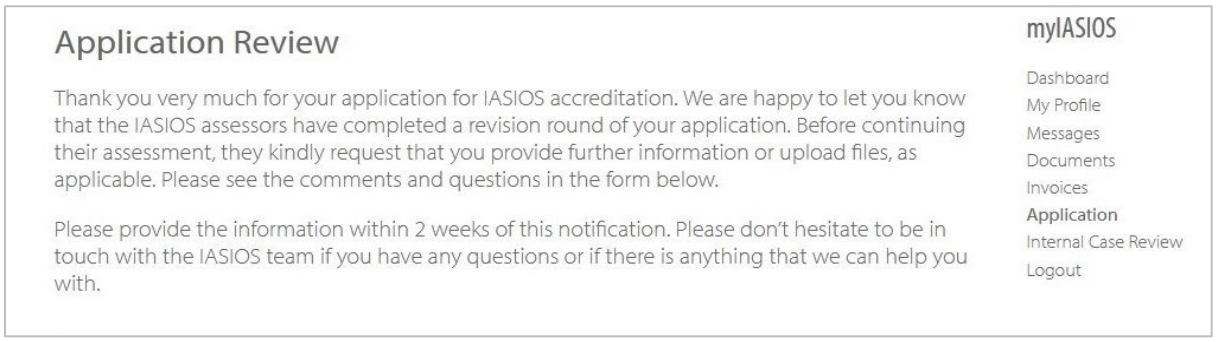


Figure 12: After your application has been reviewed

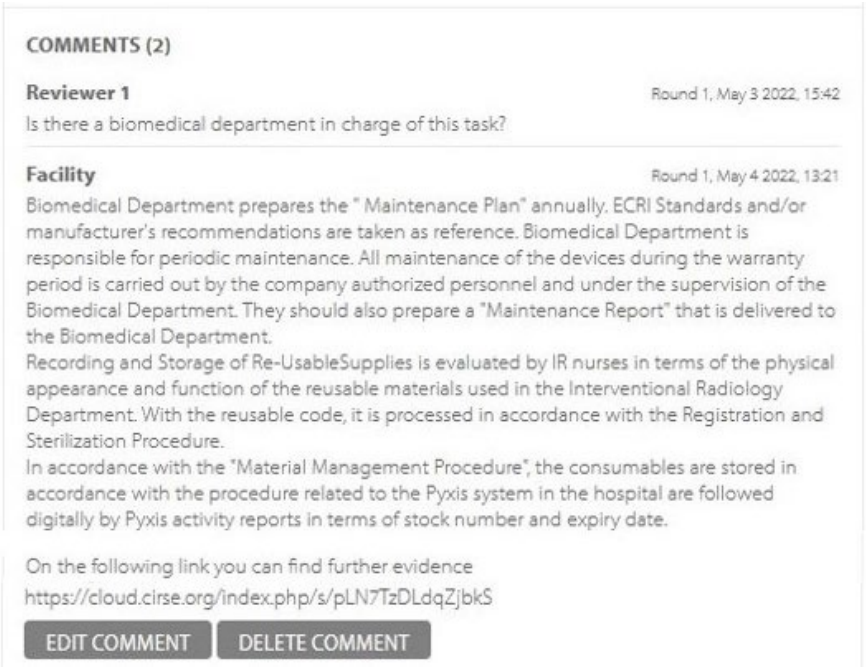


Figure 13: Responding to assessor comments

Similar to the first submission, you can see an overview of your application progress by clicking on 'Show Summary' and the percentage of your progress will be displayed at the bottom of the page.

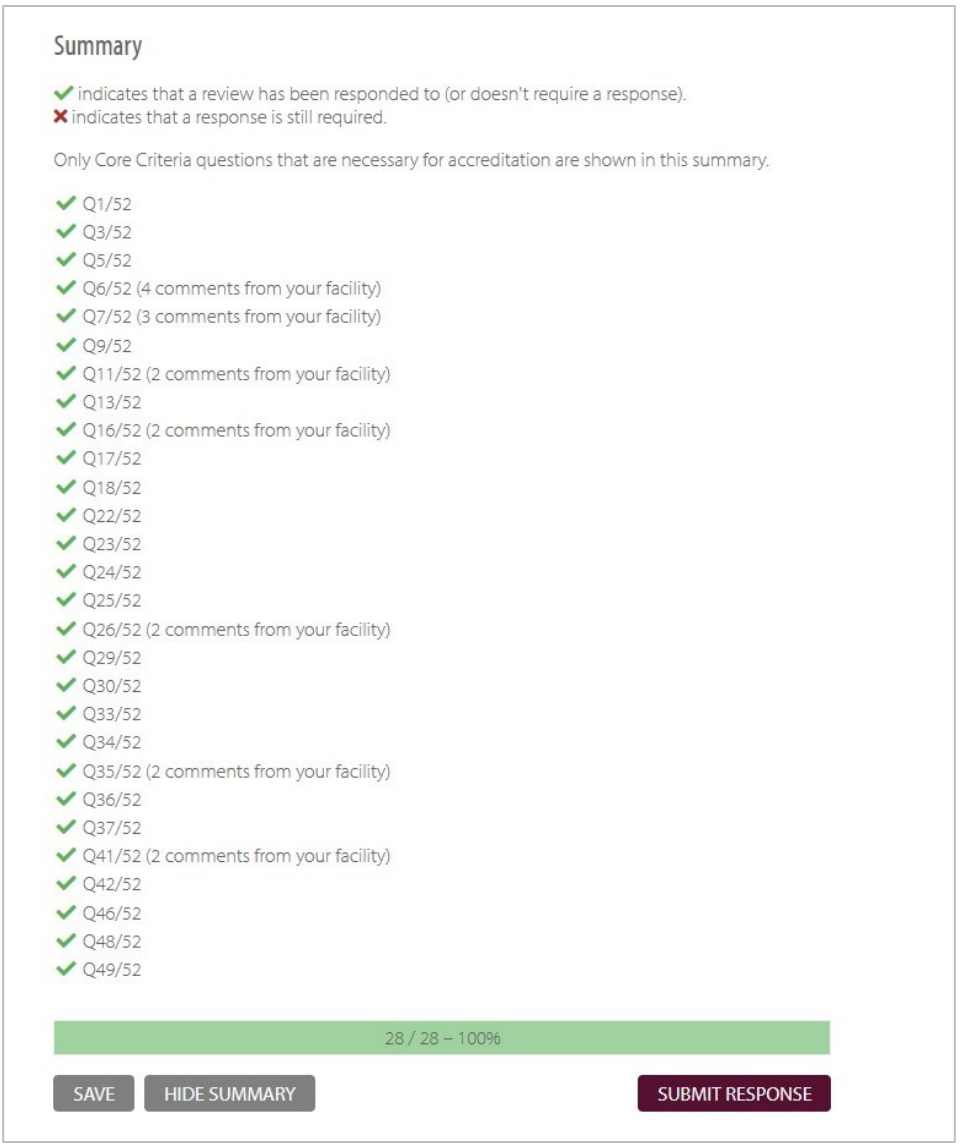


Figure 14: Ready to submit for a second review

Once you have fulfilled all the requirements and your application has been approved for accreditation by the assessors and the IASIOS Committee Chairperson, you will receive an email informing you of your accreditation status and a notification in your myIASIOS account.

2.3 Uploading and Accessing Documents

All relevant documents for the facility will be made available under 'Documents' on your myIASIOS area, which includes this Application Manual, a Marketing Manual for promoting your facilities Enrolment or Accreditation and the Standards of Quality Assurance in IO.
Please note that any documents uploaded by the facility to this area will only be visible to the IASIOS office, any supporting evidence uploaded to this area will not be visible to assessors.

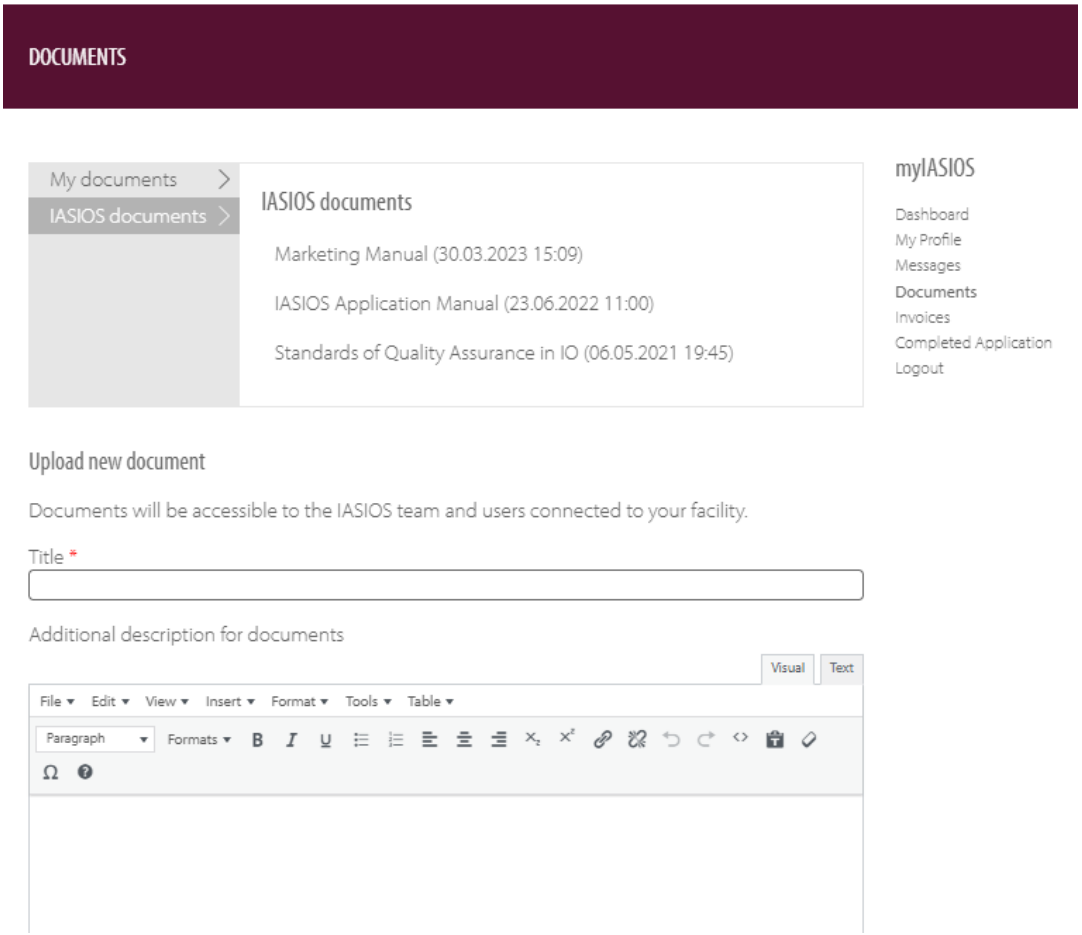


Figure 15: Uploading additional documentation

If, during the assessment process, the assessors request supporting evidence, a cloud space link will be created for your facility. You will find the link in your 'Messages' titled 'Providing Supplemental Documents and Evidence'. Please note that no documents are required with the first submission of the application.

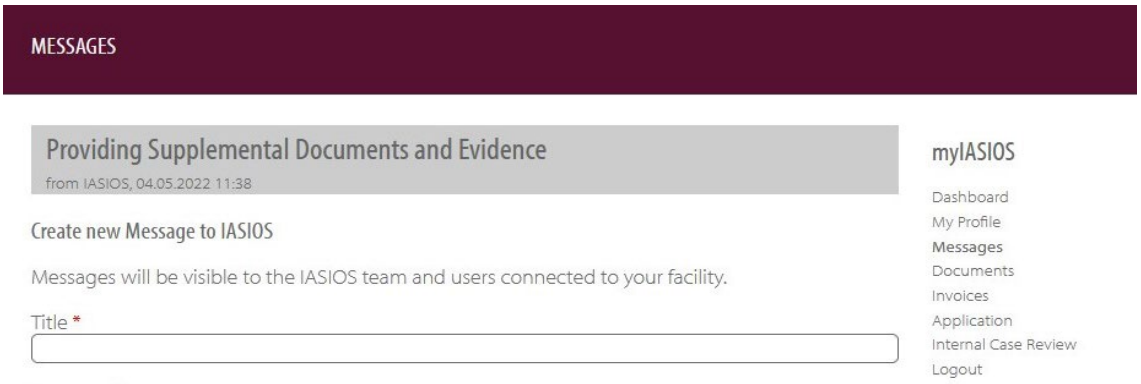


Figure 16: Uploading additional documentation for assessors

Appendix 3 – Supporting Evidence Checklist for Core Criteria

Please ensure that all supporting evidence for the core requirements are readily available to you, should you be requested to submit them as well.

Standard 1:

- ☐ 1(a): Records that staff are appropriately registered/licensed to practise
- ☐ 1(c): Records of appropriate continuing professional development activities for individual staff
- ☐ 1(e): Records listing the number of each type of therapeutic IO procedures performed per year
- ☐ 1(f): Records of outpatient consultations with an IR prior to a therapeutic procedure being scheduled and after it has been carried out
- ☐ 1(g): Records and analysis of mortality and locally specified complications

Standard 2:

- ☐ 2(b): Records of staff schedules showing that staff is being allocated time for professional development and annual leave whilst providing sufficient skilled staff to deliver a safe service when required.

Standard 3:

- ☐ 3(a): Documentation outlining the facility's record management policy, including systematic processes for tracing patient records, keeping records secure and transferring, archiving and removing records as locally applicable
- ☐ 3(c): Completed Internal Case Review form based on the information from a minimum of 30 randomly selected patient records. Please review these records against the CIRSE Minimum Dataset (MDS) to demonstrate that
    - they are accurate, comprehensive and up-to-date;
    - current versions of ICD and staging systems (or recognised alternatives) are used;
    - they are compliant with the CIRSE minimum dataset

Standard 4:

- ☐ 4(b): Documentation outlining the approach for the adoption of new and novel technologies and procedures
- ☐ 4(c): Records of meetings regarding facility management, including the main focus of the meeting (performance review, operational management, risk and safety issues) and the frequency with which they occur
- ☐ 4(d): Records of Health and Safety inspections and actions

Standard 5:

- ☐ 5(d): Evidence that input from an interventional oncologist is available for all patient cases discussed at appropriate Multidisciplinary Meetings (MDMs)

Standard 6:

- ☐ 6(a): Documentation showing the involvement of an interventional oncologist in evaluating and approving the specifications for interventional oncology equipment
- ☐ 6(b): Documentation for acceptance testing and commissioning for all interventional oncology equipment
- ☐ 6(c): Documentation outlining the arrangements for the procurement, storage and management of reusable and non-reusable devices, drugs and materials used in IO procedures
- ☐ 6(d): Maintenance programme details and records for all significant items of reusable medical equipment

Standard 7:

- ☐ 7(a): Documented patient consent policy for use in interventional oncology
- ☐ 7(b): Completed Internal Case Review form based on the information from a minimum of 30 randomly selected patient records covering at least 3 different types of tumours for patients treated with IO in the last 12 months, including:
    - Informed patient consent for interventional treatment and associated procedures;
    - Any subsequent change to the consented procedure

Standard 8:

- ☐ 8(a): Documentation of the process used to verify patient identity and match the patient to the intended treatment plan prior to each treatment session
- ☐ 8(b): Documentation of the process used for systemic equipment checks prior to use
- ☐ 8(c): Documentation of a defined system used for observing, monitoring and recording patients' vital signs during treatment
- ☐ 8(d): Completed Internal Case Review form based on the information from a minimum of 30 randomly selected patient records demonstrating:
    - A process was used to verify patient identity and match the patient to the intended treatment plan prior to each treatment session
    - A defined system was used for observing and monitoring patients' vital signs during treatment
- ☐ 8(e): Documentation of a systematic process to check single-use devices, drugs and materials before use

Standard 10:

- ☐ 10(c): Record of a written risk register showing that patient risks have been considered within the operation of the facility and the action plan addressing any outstanding risks

Standard 11:

- ☐ 11(a): Documentation of a system to manage radiation safety risks that includes:
  - Appropriate training requirements for clinicians undertaking interventional oncology procedures involving ionising radiation;
  - A documented policy that describes the management of pregnant patients who are being exposed to radiation;
  - A register of all radiation emitting equipment and radioactive sources; and
  - A register of all workers that shows the details of their licensed areas of work, specific responsibilities and records of radiation safety training and personal monitoring results

Standard 12:

- ☐ 12(a): Documentation showing that the facility records incidents of all types (including near misses), analyses the data and takes action as appropriate
- ☐ 12(b): Evidence of feedback of incidents and investigations to staff

Appendix 4 – Minimum Dataset Checklist

Please use this form to determine if patient records collected by your facility correspond to the minimum data requirements stipulated in Standard 3(c) of the CIRSE Standards of Quality Assurance document.

PATIENT DETAILS

- ☐ **First Name**
- ☐ **Last Name**
- ☐ **Gender**
- ☐ **Date of Birth**
- ☐ **Nationality (at birth)**
- ☐ **Hospital Name**
- ☐ **Responsible Interventional Oncologist**

PRESENTATION & HISTORY

- ☐ **Referral date to the Interventional Oncology service**
- ☐ **Date of Interventional Oncology consultation**
- ☐ **Symptoms recorded, if applicable**
- ☐ **Co-morbidities**
- ☐ **Family history of cancer or predisposing conditions recorded, if applicable**
- ☐ **Nutritional status** *(e.g. significant weight loss, major dietary restrictions)*
- ☐ **Performance status** *(ECOG or similar)*

CANCER

- ☐ **Primary site (ICD10)**
- ☐ **Date of diagnosis**
- ☐ **Histological subtype**
- ☐ **Differentiation** *(e.g. well, moderate, poor, undifferentiated, unknown)*
- ☐ **Laterality** *(e.g. left, right, bilateral)*
- ☐ **Most valid diagnostic method** *(e.g. clinical, tumour marker, cytology, histology (metastasis), histology (primary), imaging and other diagnostic techniques, unknown)*
- ☐ **Stage** *(T/N/M/TNM)*
- ☐ **Maximum diameter of lesion treated**

TREATMENT

- ☐ **Date of procedure**
- ☐ **Type of procedure**
- ☐ **Name of operator**
- ☐ **Intention** *(curative/palliative)*
- ☐ **Target site(s)**
- ☐ **Treatment technique**
- ☐ **Type of device used** *(make and model)*
- ☐ **Treatment parameters** *(e.g. device settings, treatment duration)*

Appendix 5 – Corrective Action Plan

Corrective Action Plan

Declined Criteria

Issue Description

Desired Outcome

Strategic Action	Person Responsible	Resources Required	Due Date	Comments