



L13.- Safety Assessment Review Process (II)

International Atomic Energy Agency



OBJECTIVE

Conducting the technical review

- *Review Team*
- *Graded approach*
- *Overall process*
- *Final review reports*





Introduction

- ✓ The regulatory decision making process may involve one or several regulatory bodies and may also be scrutinized by the public and other interested parties.
- ✓ The credibility of the process is enhanced if the regulatory body takes **a coordinated approach with interested parties in order** to observe that regulatory decisions are based on a careful and comprehensive examination of the safety assessment.





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Review Team

- ✓ Assembling a competent review team with a team leader;
- ✓ Several small teams organized by disciplines or safety areas and coordinated by a coordinator (usually the licensing officer);
- ✓ Small team supported by external consultants;
- ✓ Assistance from expert peer review:
 - *Be cautious about selection of experts*
 - *IAEA can assist*





Characteristics of the review team



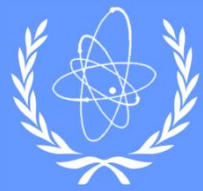
- Multidisciplinary expertise and practical experience;
- Good knowledge of the regulatory framework;
- Experience in conducting and reviewing safety assessments;
- Field experience and judgment;



Characteristics of the review team



- Familiar with international practices and guidance;
- Good understanding of the scope of the project and the context of the review;
- Comprises members whose advice will be seen by stakeholders as credible;
- Independent, with members not involved in the development of the safety assessment under review.



Some examples of expertise needed in the review team

- Radiological protection;
- Radioactive waste management;
- Medical physics;
- Industrial application of radiation sources;
- Hazard identification and categorization;
- Structural integrity and engineer systems;
- Geosciences (hydrogeology, geology, geotechnical, geochemistry etc.);
- Transport of radioactive materials;
- Management system;
- Security and safeguards;
- Etc.





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Graded approach

- ✓ The level of scrutiny and scope of the regulatory review of a safety assessment should follow a graded approach.
- ✓ To facilitate the application of the graded approach, the regulatory body should consider establishing a set of deterministic screening criteria to categorize facilities or activities according to their safety significance.





Graded approach

Decisions about the depth and extent of the review process should take into account the following:

- *The likelihood and magnitude of exposures of workers and/or members of the public arising from planned processes, or from anticipated operational occurrences or accidents;*
- *The complexity, safety significance and maturity of the proposed processes;*
- *Relevant experience from similar facilities or activities (national and international);*
- *The scope of the facility or activity being assessed ;*
- *Technical or safety concerns of other competent authorities;*





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Main steps of the technical review

A regulatory review will normally have four phases:

1. *An initial phase, prior to receipt of any documents from the applicant (initial planning);*
 - Stablishing the team
 - Review Plan
 - Agenda
 - Etc.





Main steps of the technical review

2. A preliminary review phase, during which the regulator will make an initial assessment of the submitted documents;

- Review for completeness in terms of regulatory requirements;
- Structure and logic of the document;
- Clearly written;
- Traceable to supporting documents and references
- List of contributors;



Main steps of the technical review

3. *A main technical, detailed review phase;*
 - Step by step review;
 - Independent calculations (where appropriate);
 - Conclusions and recommendations;
4. *A completion phase.*

The completion phase of the review will include the development of a final review report.





Independent assessment by the regulator

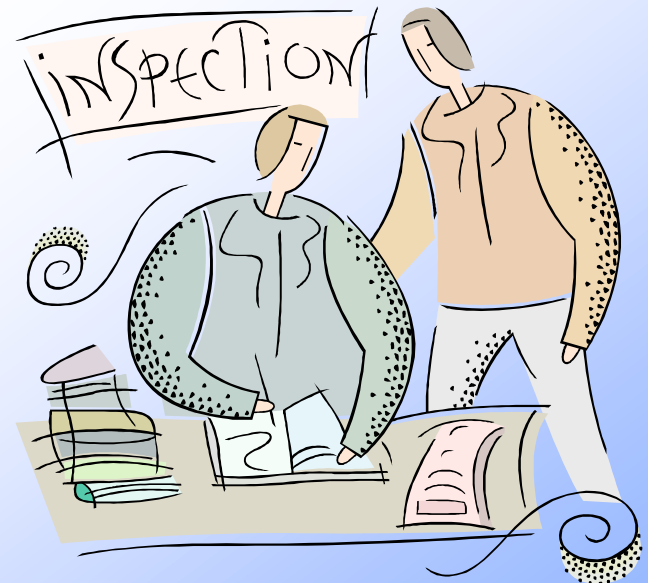
- ✓ Enhance regulator's understanding of issues that are most important to safety.
- ✓ Test the reproducibility of the external consultant's results.
- ✓ Derive specific regulatory limits.
- ✓ Extend the analysis performed by the external consultant using different set of parameters and perform own sensitivity analysis.
- ✓ Enhances credibility of the regulator.





Inspection

In addition to the assessment of documentation submitted by the applicant, the regulatory review of the safety assessment may require inspection of the facility or activity, if this is in the construction phase or already exists, in order to verify the accuracy of the safety assessment as a description of the facility and its operational features.





Internal screening of the review comments

Comments generated by individual team members have to be discussed by team members before they are sent to the implementer. This is to:

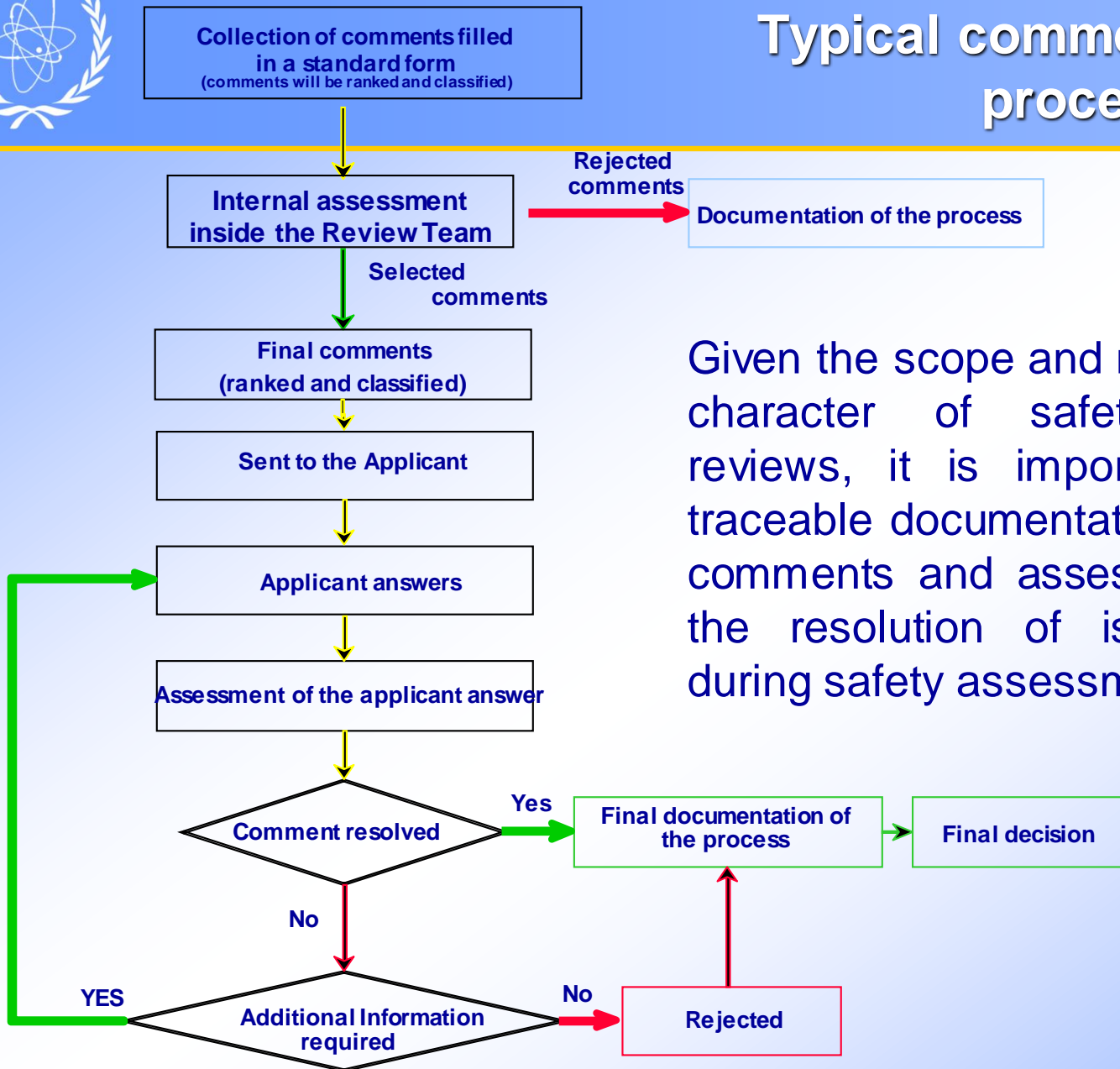
- ✓ *Determine the relative significance of the comments,*
- ✓ *Ensure appropriate level of consistency,*
- ✓ *Prevent unnecessary duplication,*
- ✓ *Keep the review team informed of the review results and the main issues associated with the safety assessment.*

This process can lead to internal and external conflicts that have to be resolved using appropriate conflict resolution approaches.





Typical comment resolution procedure



Given the scope and multi-disciplinary character of safety assessment reviews, it is important to ensure traceable documentation of all review comments and assessments, and of the resolution of issues identified during safety assessment reviews



Compilation and communication of the review comments

- ✓ Comments should be grouped under topics consistent with the structure of the safety case or presented in a chronological manner;
- ✓ Comments should be identified with an ID number for future tracking;
- ✓ Comments should be sent along with a summary report highlighting the main deficiencies and associated significance;
- ✓ All communication with the implementer should be through the team leader who is designated as single point of contact;



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Final Review Report

The completion phase of the review will include the development of a final review report.

The regulatory body should consider including the following in the final review report:

1. Background to the review, including:

- ✓ Summary information about the facility or activity,
- ✓ The regulatory framework in which the review was conducted,
- ✓ The purpose of the review,
- ✓ The approach to the review, and
- ✓ The review process followed.

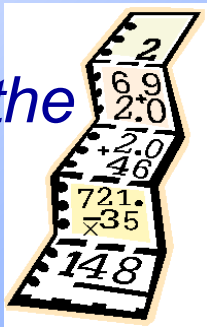




Final Review Report

2. Key review findings concerning high level issues such as:

- ✓ *The safety strategy,*
- ✓ *The context,*
- ✓ *Approach and results for the safety assessment,*
- ✓ *The treatment of uncertainty (in scenarios, models, parameters),*
- ✓ *Risk management and optimization ,*
- ✓ *Appropriate limits and conditions,*
- ✓ *And the programme for the future development of the safety assessment.*





Final Review Report

3. Key review findings concerning the main technical areas of review, such as:
 - ✓ *Design*
 - ✓ *Equipment main features*
 - ✓ *Commissioning*
 - ✓ *Technical aspects of operation*

4. Key review findings concerning compliance with the main regulatory criteria and guidance.



Final Review Report

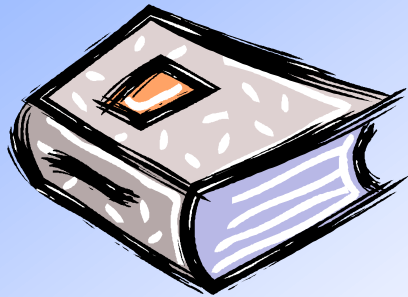
5. Conclusions of the review with regard to issues to be considered in licensing or authorization, such as:
- ✓ *Compliance with regulatory requirements*
 - ✓ *Further information to be provided by the applicant,*
 - ✓ *Revised safety assessment work,*
 - ✓ *Monitoring and other controls on the site or the sources,*
 - ✓ *Restrictions on the source and discharge inventory,*
 - ✓ *Risk management*



ceiling crane for removal of waste



Final Review Report



6. A list of unsolved issues and uncertainties.
7. A list of references, including reference to documents considered in the review, and underlying review reports that support the final review report.
8. Appropriate information to demonstrate the credibility of the individuals making up the review team.



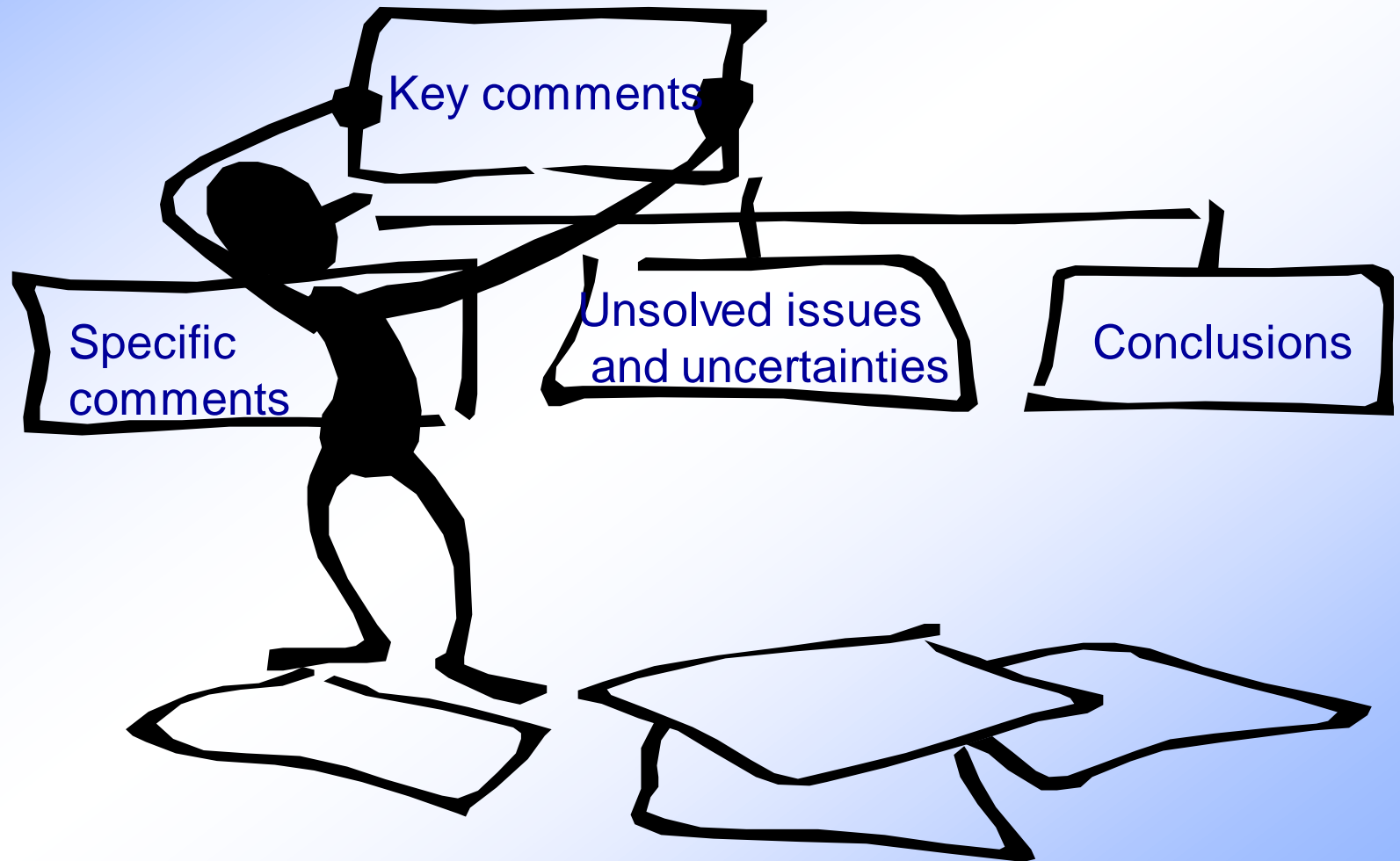
Final Review Report

When documenting the review comments and assessment, the following should be ensured:

- ✓ *The approach taken in the development of the safety assessment and the results of that approach should be briefly summarized;*
- ✓ *The basis for the comments should be clearly stated using a standard format, and each comment should be given a unique identifier for ease of cross-reference;*
- ✓ *The relevance of the comment to safety, understanding of systems and/or control of the facility should be noted;*
- ✓ *Actions necessary to resolve the issues identified in the review comments should be clearly stated.*

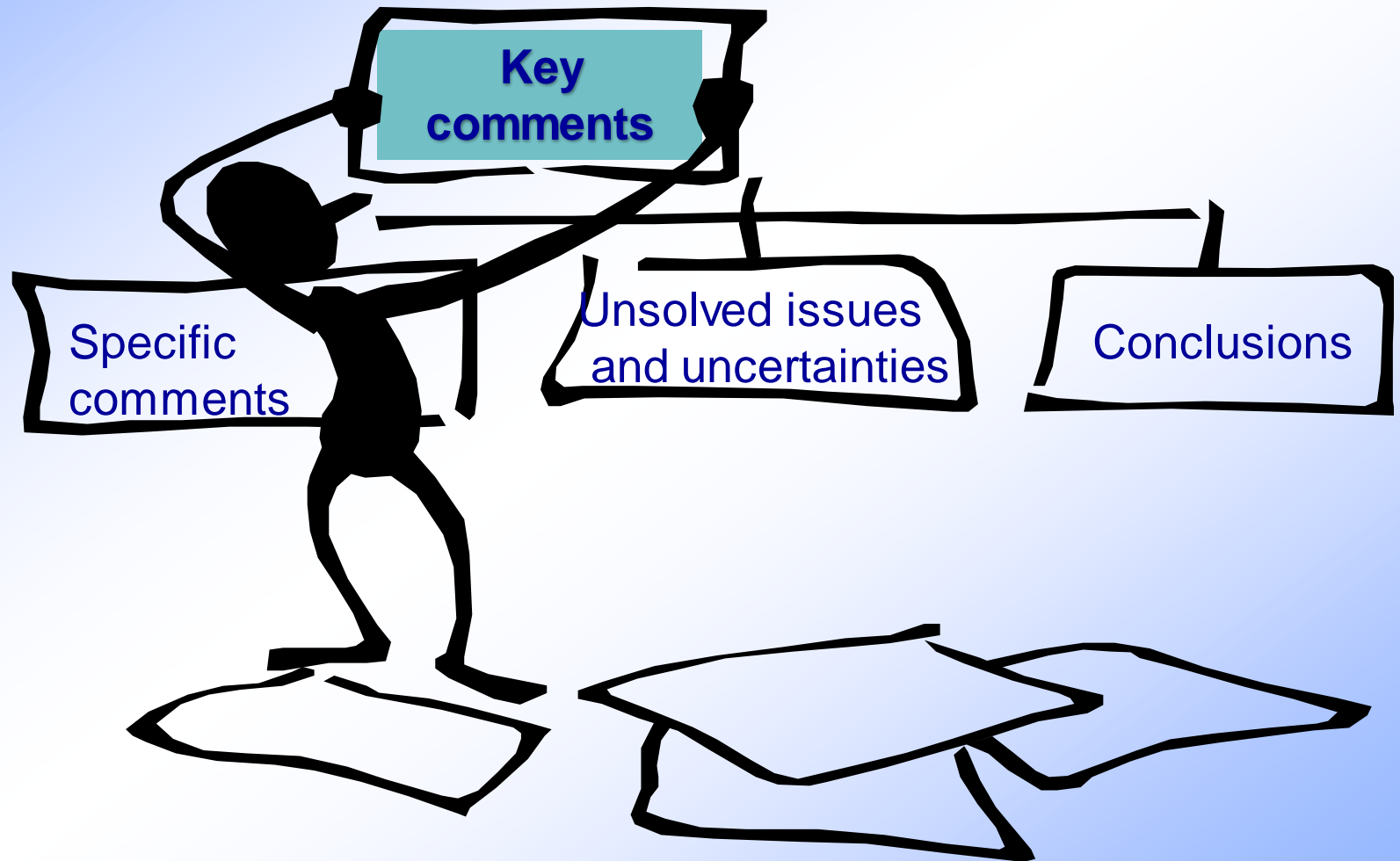


Main results of assessment





Main results of assessment





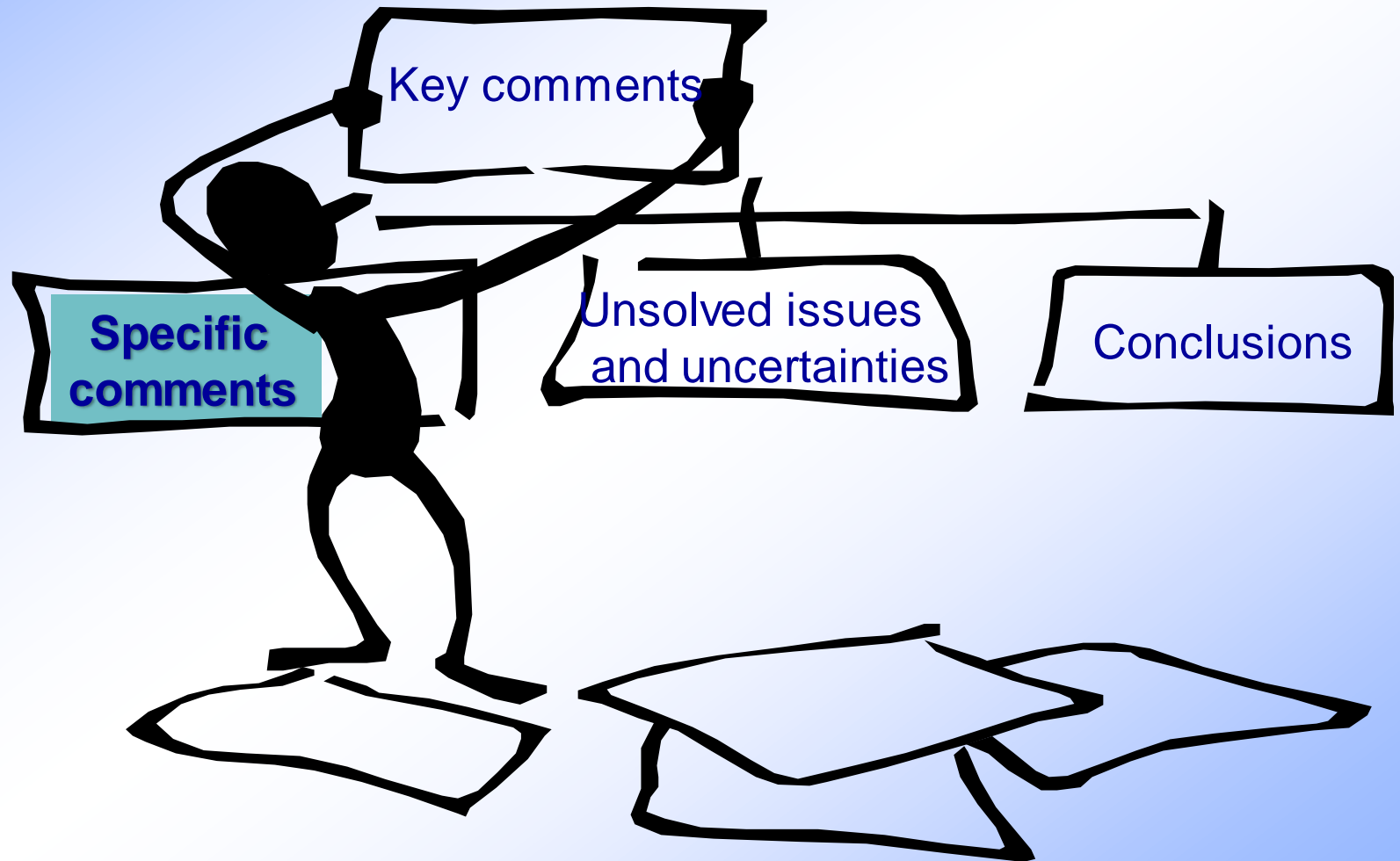
Main results of assessment: key comments

A description of each of the areas reviewed should be documented, with reference to the following areas:

- ✓ *The safety strategy,*
- ✓ *The assessment context,*
- ✓ *Approach and results for the safety assessment,*
- ✓ *The treatment of uncertainties (in scenarios, models and parameters),*
- ✓ *Risk management and optimization,*
- ✓ *Compliance with the main regulatory criteria and guidance,*
- ✓ *Appropriate limits and conditions, and*
- ✓ *The programme for the future development of the safety case.*



Main results of assessment





Main results of assessment: Specific comments

These are more detailed review findings concerning:

- ✓ *The main technical areas of review,*
- ✓ *The characterization of the facility,*
- ✓ *Potential influence of the installation to the environment.*



**Industrial
cyclotron**



Main results of assessment





Main results of assessment: Unsolved issues and uncertainties

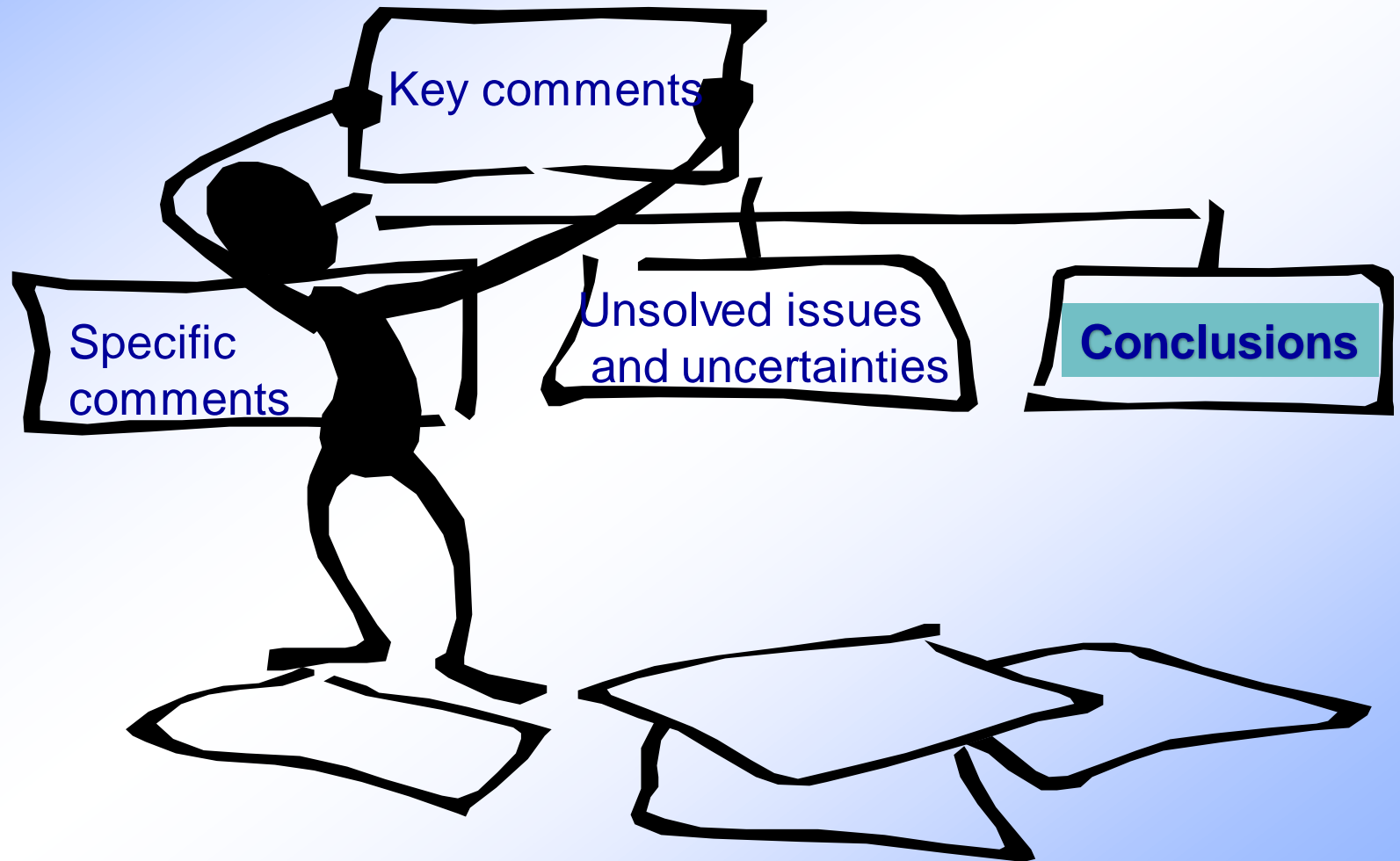
A description of each of the areas reviewed should be documented, with reference to the following topics:

- ✓ *Comments about issues that remain unsolved.*
- ✓ *Their relative safety significance should be noted together with the actions that should be taken by the applicant to resolve the comments, if necessary.*
- ✓ *Any conditions for authorization of the facility should be described and justified here.*





Main results of assessment





Main results of assessment: Conclusions

The conclusions of the review should be stated with regard to issues to be considered in licensing or authorization, such as:

- ✓ *Compliance with regulatory requirements*
- ✓ *Further information to be provided by the applicant,*
- ✓ *Revised safety assessment work,*
- ✓ *Monitoring and other controls on the site or the sources,*
- ✓ *Restrictions on the doses, and discharge inventory,*
- ✓ *Risk management, and*
- ✓ *In addition, recommendations for conditions for authorization should be listed.*



