IAEA-TECDOC-1217

Assessment by peer review of the effectiveness of a regulatory programme for radiation safety

Interim report for comment

IAEA

May 2001

32/26

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INTERNATIONAL ATOMIC ENERGY AGENCY IAEA

May 2001

The originating Section of this publication in the IAEA was:

Radiation Safety Section
International Atomic Energy Agency
Wagramer Strasse 5
P.O. Box 100
A-1400 Vienna, Austria

ASSESSMENT BY PEER REVIEW OF THE EFFECTIVENESS OF A REGULATORY PROGRAMME FOR RADIATION SAFETY
IAEA, VIENNA, 2001
IAEA-TECDOC-1217
ISSN 1011–4289

Printed by the IAEA in Austria
May 2001

FOREWORD

Since publication of the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (the BSS), published as Safety Series No. 115 in 1996, many Member States have engaged in an extensive effort to enact legislation and establish a regulatory programme to implement its requirements. In this connection, the International Atomic Energy Agency (IAEA) started in 1996 a technical co-operation programme (Model Project on Upgrading Radiation Protection Infrastructure) to improve the infrastructure for radiation protection and safety of radiation sources in more than 50 Member States, including as a first priority assistance for strengthening their regulatory programmes for radiation safety.

Subsequently, the IAEA's General Conference adopted, on 25 September 1998, a resolution (GC(42)/RES/12) which encouraged all Governments "to take steps to ensure the existence within their territories of effective national systems of control for ensuring the safety of radiation sources and the security of radioactive materials".

Assessment of the effectiveness of a regulatory programme for radiation safety is an important part of quality assurance both with respect to implementation of the BSS and meeting the objectives of the 25 September 1998 General Conference resolution. This TECDOC provides a methodology by which the status of a regulatory programme for radiation safety can be assessed and areas where improvements are necessary or useful can be identified. It can be used by countries participating in the model project for strengthening the effectiveness of the regulatory framework as well as by other Member States and by non-member States.

This TECDOC was developed during the course of two consultants meetings held in late 1997 and early 1998, and a Technical Committee meeting held in early 1999. An additional consultants meeting was held in early 2000 to include in this report the experience gained by the use of the above referred methodology during the peer review missions carried out in the second half of 1999 to 14 Member States participating in the Model Project. The experience gained in the IAEA peer review missions carried out during the second and third quarters of 2000 in several countries in the Asia region was taken into account in the final version of this TECDOC.

The IAEA officer responsible for this publication was A. Bilbao-Alfonso of the Division of Radiation and Waste Safety.

EDITORIAL NOTE

The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

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CONTENTS

1. INTRODUCTION

1.1. Background

The preamble to the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) state that the Standards are based on the presumption that a national infrastructure is in place which enables the Government to discharge its responsibilities for radiation protection and safety. Essential parts of the national radiation safety infrastructure are: laws and regulations; a Regulatory Authority empowered to authorize and inspect regulated activities and to enforce the laws and regulations; sufficient resources; and adequate numbers of trained personnel.

A national radiation safety infrastructure includes all persons, organizations, qualified experts, systems, documents, facilities and equipment, and technical services that are, in whole or in part, dedicated to radiation protection and safety. It includes the Regulatory Authority[1] whose principal functions are identified in the preamble to the BSS. This TECDOC is part of a series of documents prepared by the IAEA to assist Member States in organizing and operating a regulatory programme to implement the BSS. While the requirements of the BSS do not apply directly to a Regulatory Authority, managerial aspects of protection and safety addressed in the BSS, particularly quality assurance which includes the concept of safety culture, are relevant for the Regulatory Authority to ensure effectiveness of the whole radiation safety infrastructure.

Quality assurance is a continuous process. Within a regulatory programme, it should involve all levels of staff and management. It includes regular management oversight, special supervisory audits, and periodic reviews and assessments of regulations, guides and policies. Additionally, there should be formal, periodic assessments conducted by persons who are, to the extent practicable, independent of the regulatory programme being reviewed and who report results to a level of management above those having direct responsibility for the programme. The resources for quality assurance need to be included in the budget for the regulatory programme.

The guidance contained in this document includes a level of detail that is appropriate for an in depth assessment. The scope and depth of the assessment, however, should be scaled to the prevailing situation. In many instances, it will not be necessary to go into great detail if areas requiring high priority improvement are identified early. There may be little benefit in continuing assessment beyond such findings because of limited capacity of the Regulatory Authority staff to make the most needed improvements. The depth of subsequent assessments may increase as the programme develops and matures.

An assessment conducted by persons experienced in regulatory activities might also be considered as an on-site training opportunity, particularly for staff of Regulatory Authorities which are in the earlier stages of development. It provides an opportunity for staff to learn on the basis of critiques of their authorization and inspection work provided by a senior member of the peer review assessment team (hereinafter "the Review Team"). It has the particular advantage of being a very personal training opportunity which is directly related to real cases or situations rather than an abstract class room exercise.

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[1] Regulatory Authority: An authority or authorities designated or otherwise recognized by a Government for regulatory purposes in connection with radiation protection and safety.

1.2. Objective

The objective of this TECDOC is to provide guidance on the assessment of the effectiveness of a regulatory programme for radiation safety, and thereby enable recommendations to be made which are intended to strengthen the programme. In broad terms, an effective regulatory programme for radiation safety is one which is organized and operated in a way such that its legislative mandate is fulfilled. The specific wording of such legislative mandates vary from country to country, but a fundamental objective embedded in them should be to protect the health and safety of people while permitting the beneficial uses of ionizing radiation.

1.3. Scope

This document covers assessment of those aspects of a radiation protection and safety infrastructure that are implemented by the Regulatory Authority for radiation sources and practices using such sources and necessarily includes those ancillary technical services, such as dosimetry services, which directly affect the ability of the Regulatory Authority to discharge its responsibilities. The focus of the guidance in this TECDOC is on assessment of a regulatory programme intended to implement the BSS. The BSS address transportation and waste safety mainly by reference to other IAEA documents. When conducting an assessment, the Review Team members should be aware of the latest IAEA documents (or similar national documents) concerning transportation and waste safety and, if appropriate, nuclear safety, and take them into account to the extent applicable when assessing the effectiveness of the regulatory programme governing radiation protection and safety of radiation source practices in a particular State.

1.4. Structure

Following this introduction the TECDOC starts with general information about assessments of effectiveness as part of quality assurance. It then identifies the various areas that should be included in an assessment of the effectiveness of a regulatory programme for radiation safety, depending on its phase of development. From there, it covers how to prepare, conduct and report an assessment; a methodology used to assess effectiveness; and how to evaluate and prioritize the findings and recommendations. Appendix I provides questions to be used in connection with performance indicators. Appendix II identifies the kinds of information that the Review Team should obtain and become familiar with prior to its meetings with the Regulatory Authority staff. Appendix III provides checklists to assist in the assessment of regulatory staff performance. Appendix IV provides supplemental guidance to the Review Team during the assessment of regulatory programmes for radiation safety which are in the organizational phase. The Annex identifies the kind of information for which the Regulatory Authority Information System (RAIS) database can be used.

2. GENERAL

The main purposes of legislation governing radiation sources are to allow beneficial uses of ionizing radiation, and to provide for adequate protection of people in current and future generations against the harmful effect of ionizing radiation and for the safety of radiation sources. The BSS contain the principles and criteria which need to be applied for adequate protection and safety. The legislation should establish a Regulatory Authority with

responsibility and authority to ensure that the appropriate radiation protection and safety principles and criteria, namely those of the BSS, are applied by those possessing and using radiation sources. The legislation should also provide for any other supporting mechanisms needed to ensure adequate radiation protection and safety. Collectively, the Regulatory Authority and the directly relevant supporting mechanisms constitute the regulatory programme.

Effectiveness, as used in this TECDOC, is simply a measure of the degree to which the regulatory programme, and chiefly the Regulatory Authority, is successful in ensuring adequate radiation protection and safety, and in discharging other assigned responsibilities of the legislative mandate. Both qualitative and quantitative assessments are employed to characterise the status of effectiveness for specific components of the regulatory programme for radiation safety.

The assessment involves an examination of the various components and activities of a regulatory programme for radiation safety as they are established, organized and implemented by the Regulatory Authority in order to determine whether they are achieving their intended purposes, and to identify areas and make recommendations where adjustments might be made to optimise effectiveness.

An independent assessment, i.e. an assessment conducted by experts who are independent of the Regulatory Authority, enhances the objectivity of quality assurance covering a regulatory programme for radiation safety. There may be programmes, for example, where inspections of authorized users have not identified areas needing corrective actions and where fewer accidents are reported than would normally be expected for the number of regulated source users. This can mean either that the regulatory programme is very effective or conversely, that it is very poor in identifying problems. The assessment should be able to determine which is the case and why.

Conclusions and recommendations resulting from an assessment will be drawn in part from data and other quantitative information obtained from operations within the regulatory programme and in part from reports to the Regulatory Authority from authorized users. Many conclusions and recommendations, however, will be qualitative, resulting from, for example, observation of an inspector's performance during an inspection or a retrospective analysis of a license application.

Because much of an assessment will necessarily be qualitative, it is important that it be conducted by persons who, collectively, have a good understanding and extensive practical experience with the organization, and operational and technical aspects of a regulatory programme.

3. THE REGULATORY PROGRAMME AND THE STATUS OF ITS DEVELOPMENT

3.1. The regulatory programme and its effectiveness

To assess regulatory programme effectiveness it is necessary to include those areas of the country's radiation safety infrastructure that bear directly on it, even though some of these areas may not be strictly a part of the regulatory programme.

The assessment of effectiveness should cover the following areas, where those items in normal type indicate components of the regulatory programme itself and those in *italics* are other, directly relevant areas of the infrastructure:

1. *Laws*/Regulations and Regulatory Authority
2. Notification
3. Authorization (Licensing/Registration)
4. Inspection
5. Enforcement
6. Emergency Response
7. Investigation and Follow-up
8. *Technical Services*
9. *Co-ordination and Co-operation*
10. Staffing and Training
11. Funding
12. Information Dissemination

These are the principal areas to be evaluated, however they do not have equal weight in the assessment. The first six areas on the list of twelve can be considered as the core areas of a regulatory programme for radiation safety. If one of these core areas is ineffective when the programme is operational, then the programme itself can not be considered to be effective. If each of the first six areas is at least minimally effective, there is likely to be some capability in, or support from, the other six areas.

In a consideration of the effectiveness of a regulatory programme for radiation safety, account should be taken of the country's needs, which will be determined by the extent of use of radiation practices and the resources available to meet those needs. Thus the expectation for achievement, particularly in the last six areas of evaluation should be greater in an absolute sense for a wealthy, advanced nuclear technology country than may be the case for some other countries. Nevertheless, there are minimum requirements for a regulatory programme to be regarded as effective.

3.2. Status of regulatory programme development

A regulatory programme for radiation safety can be generally characterised as being in one of three phases of development, namely:

(a) Organizational phase

At this phase, it would be expected that:

- law is either in place, or being developed;
- regulations based upon the BSS are being prepared, possibly at a late stage in drafting;
- a Regulatory Authority, established by law or temporarily appointed, is engaged in an organizational process including, for example, assignment of responsibilities and development of an operating structure;
- some staff members are already appointed within the Regulatory Authority, and staff training is underway;

- efforts are already being made to require notification of possession or use of radiation sources;
- authorization, inspection and enforcement programmes are in the early stage of development;
- arrangements for emergency response and investigation[2] programmes are being planned;
- essential technical services are in the process of being established and others are under evaluation; and
- the needs for co-ordination and co-operation with other relevant organizations are in the process of being identified.

The organizational phase of the regulatory programme for radiation safety is very critical since it sets the stage for how it will operate in the future and, therefore, has a substantial bearing on its future effectiveness. While the above list identifies in general what should be transpiring during the organizational phase, there are some particular considerations which the Review Team should bear in mind and address as may be appropriate during this important stage of review. These are discussed in Appendix IV.

(b) Implementation phase

At this phase, it would be expected that:

- law and regulations based upon the BSS are in place;
- the organizational structure at the Regulatory Authority is established and the core of the staff is appointed and trained, and plans for subsequent training are established;
- notification of the possession and use of radiation sources is virtually complete, and authorizations are being issued, particularly for the more hazardous practices;
- inspection and enforcement programmes are in place and implementation has been initiated;
- emergency response and investigation programmes are at the early stages of implementation;
- the most essential technical services are available and others are scheduled to become available; and
- co-ordination and co-operation arrangements with key organizations, e.g. customs, have been established.

Assessment would be entirely appropriate to this implementation phase, and should be able to establish whether the Regulatory Programme for radiation safety is effective.

(c) Operational phase

At this phase of development, the principal components of the regulatory programme for radiation safety have been established and are fully operational, but are possibly at different stages of maturity.

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[2] As used in this TECDOC, investigation means a systematic examination or inquiry into the circumstances related to an accident with significant radiological consequences, a significant exposure, or a situation which involves degraded safety or security with the potential for significant radiological consequences, e.g. a lost source, faulty equipment. An investigation includes a determination of causes, needed corrective actions and lessons learned to prevent similar occurrences.

4. GUIDANCE TO REVIEW TEAM MEMBERS ON THE PREPARATION AND CONDUCT OF AN ASSESSMENT AND REPORTING OF FINDINGS

4.1. Preparing for the assessment

Once it has been decided by the Government or the Regulatory Authority to conduct an assessment of the effectiveness of the regulatory programme for radiation safety, advance preparation is essential if the Review Team is to be successful. The assessment is resource intensive for both the Regulatory Authority staff and the Review Team members. Consequently, it should be carefully planned well in advance, and conducted over a relatively short time. Most assessments of a regulatory programme for radiation safety will be conducted by 2–3 person Review Teams that are on-site for approximately 1–2 weeks.

These are often likely to be language and organisational difficulties that extend the necessary discussions. Moreover, a primary feature of a peer review is that the report, or at least the factual content of the report, should be acceptable to all parties. This is impossible unless time is available for preparation and discussion of a good draft report. It is also stressed that a peer review consists of much more than a 'tick box' collection of answers to pre-determined questions. The questions provide a structure but the responses provoke ongoing queries and many value judgements. Time should also be provided for the Review Team to meet each other and play the review.

The Review Team should be composed of knowledgeable, technical managers from outside of the regulatory programme, one of whom is appointed as the leader. It will sometimes be necessary to use experts from other Member States to fulfil these requirements.

The steps that should be taken in preparation for an assessment are as follow:

(a) define areas to be reviewed and the related questions (see Appendix I);
(b) appoint Review Team members and designate the leader;
(c) identify the principal Government and/or Regulatory Authority contact (the counterpart) to interface with the Review Team;
(d) reach agreement with the Regulatory Authority on the schedule for the assessment and how it will be conducted;
(e) designate programme area assignments of Review Team members;
(f) request advance information from the counterpart (see Appendix II); including detailed explanation to the related questions (see Appendix I);
(g) review information provided, and identify questions/issues to be addressed by the Review Team when the on-site visit;
(h) complete a preliminary review plan and confirm Review Team assignments; and
(i) complete logistical arrangements for the on-site visit.

An independent assessment requires the motivation and the full support of the Regulatory Authority staff. The results of the assessment should enhance the quality of the regulatory programme for radiation safety in the particular State, and therefore it is in the interest of the entire Regulatory Authority staff to co-operate in making it successful.

4.2. Advance information

Before conducting an assessment in a particular State, general information about its regulatory programme for radiation safety should be obtained from the Government or the

Regulatory Authority. This advance information (see Appendix II) will help prepare Review Team members for their tasks. It will also reduce the resource burden imposed on the Regulatory Authority's staff and optimise the Review Team members' efforts while on-site.

When requesting prior information, the effort that the Regulatory Authority will expend to provide it should be considered. This may be particularly important where the language used in the Member State, and in its legislation and other documents, is different to that of the members of the Review Team. It is appropriate to request broad, comprehensive information about the regulatory programme (such as an organizational chart or description of the Regulatory Authority's structure) and specific documents essential to conducting the assessment (such as copies of the laws and regulations), in advance of the assessment.

In this respect, it would be beneficial if the basic information to which the questions in Appendix I refer is available also to the Review Team prior to the review commencing. This would familiarise the Review Team with what to expect in the country that they are to review. Perhaps more importantly, it would be enable the Review Team to structure and concentrate their own questioning and their review around those areas of information that are either lacking or require further explanation. To achieve this, the counterpart in the country prior to the review should provide into an information sheet the explanation to the questions at Appendix I, as well as copies of the types of documents listed in Appendix II.

More detailed, specific information (such as authorization files and inspection documentation) may be obtained after the Review Team arrives on-site. The prior information requested should be limited to that which is readily available. All requests for information place an administrative burden on the Regulatory Authority. Therefore, care must be exercised to avoid asking for information which is unlikely to be relevant.

4.3. Conducting the assessment

The on-site assessment (which is usually conducted at the Regulatory Authority headquarters) should begin with an entrance meeting with the head of the Regulatory Authority and/or the counterpart, as well as with the managers of the various regulatory programme areas and principal staff involved. This first meeting should include a discussion of the scope of the assessment, how it will be conducted and how findings will be reported. During it, the Review Team should be introduced to staff and familiarised with the Regulatory Authority's organization, functions and powers, staffing, facilities and equipment. At this point, the Regulatory Authority should furnish any additions or changes to the advance information provided.

The on-site phase of the assessment includes analysing data, examining documents, visiting appropriate facilities/offices and interviewing Regulatory Authority managers and other staff. The Review Team members should normally work independently for efficiency and to minimise the disruption caused by being on-site. However, the Review Team members should frequently share information so that a picture of the regulatory programme for radiation safety can begin to emerge at an early stage, and to help them decide what areas should be examined in greater depth.

The Review Team members should keep an accurate record of files and data examined, interviews conducted and visits of facilities/offices of relevant radiation users and technical support services carried out, etc., so that the basis for findings, conclusions and

recommendations can be adequately documented in their report. The Review Team leader should meet frequently (usually daily) with the counterpart to discuss progress, findings and direction of the assessment. Toward the end of the assessment, the Review Team should begin to develop recommendations and assign priorities to them. (See Section 6.2 for a suggested method of prioritization of recommendations).

Upon completion of its work on-site, the Review Team should hold an exit meeting with the Regulatory Authority management and principal staff involved to discuss the findings, conclusions and recommendations likely to be included in its report, and to agree any outstanding discrepancies, determine missing information and take into account any comments regarding the conduct of the assessment.

The following summarises the steps of the assessment, approximately in the order in which they should take place. Several of these steps may take place concurrently:

(a) provide time for the Review Team to meet each other and plan the review before the entrance meeting with the counterpart's staff;
(b) hold an entrance meeting with Regulatory Authority management and/or counterpart, and the principal staff involved;
(c) become acquainted with members of the Regulatory Authority staff and familiar with the staff organization and responsibilities and Regulatory Authority facilities and equipment;
(d) carry out visits to appropriate facilities/offices of relevant radiation users/technical support services, as necessary;
(e) observe inspectors' performance during inspections;
(f) review selected authorization files, inspection files, investigation files, enforcement procedures, etc.;
(g) interview staff;
(h) review quantitative information[3];
(i) define the findings;
(j) formulate conclusions and recommendations;
(k) discuss the initial findings with the Regulatory Authority management, and/or counterpart, and principal staff involved; and
(l) conduct an exit meeting with the Regulatory Authority management, and/or counterpart, and principal staff involved for discussing any discrepancies or additional issues and for describing preliminary findings, conclusions and recommendations, as well as the priority of each recommendation.

4.4. Reporting the assessment findings

The final report of the Review Team should be available as soon as practicable after completion of the on-site assessment in order for it to be most pertinent and useful. Observations about each regulatory programme area should be provided in sufficient detail for a reader to understand the basis for any recommendations. Documents which supplement and

[3] For example, all of the Member States that are included in the Model Project have received a computerized system, developed by the IAEA and known as the Regulatory Authority Information System (RAIS), to manage regulatory information. Some of the details of the information contained in RAIS are in the Annex.

support the main text should be included as attachments to the report[4]. The final report should also identify notable "good practices" which were found during the assessment and it should also report "areas for improvements". The Regulatory Authority should be provided with two opportunities to comment on the reported results of the assessment. These will occur during the exit meeting and on receipt of the draft report prior to its being issued as a final report. The final report should include comments about the conduct of the assessment, and the validity of the findings, conclusions and recommendations provided by the Regulatory Authority.

The final report should be sent to the Government at the level which requested the assessment. The head of the Regulatory Authority should be among those who receives a copy of the final report.

5. METHODOLOGY TO ASSESS THE EFFECTIVENESS OF THE REGULATORY PROGRAMME

The assessment requires a detailed analysis of effectiveness within each of the principal areas of evaluation that are listed in paragraph 3.1. This assessment is achieved by establishing a series of performance indicators illustrating the status of actual performance, which then can be compared to performance criteria for each of these principal areas.

5.1. Role and use of performance indicators

The assessment of the effectiveness of a regulatory programme for radiation safety is based upon both qualitative and quantitative information which reflects performance. As used in this document, the term "performance indicator" means qualitative and/or quantitative information that can be compared against performance criteria in order to assess the effectiveness of the regulatory programme. Performance indicators are derived from the Regulatory Authority's answers to a series of questions developed for use by the Review Team.

Answers to the questions in Appendix I provide the main basis for the assessment. Supplementary questions might be needed, depending on the scope of the assessment, the quality of information available, or the need to examine a potential problem more thoroughly.

Checklists are contained in Appendix III as an aid for the Review Team to better assure the completeness of the assessment, particularly as it pertains to staff performance. These checklists cover some key Regulatory Authority areas to be examined, namely:

1. **Authorization Files,** to provide an overview of the quality and effectiveness of the authorization process;
2. **Inspection Techniques,** whereby a member of the Review Team accompanies an inspector from the Regulatory Authority to observe an inspection;
3. **Inspection Reports,** to provide an overview of the quality and effectiveness of information, data, and actions resulting from inspections; and
4. **Investigation Documents,** to provide an overview of the quality of the investigation information, data and analyses, and the effectiveness of follow-up procedures.

[4] e.g. the data from RAIS.

Since many points contained in Appendices I and III require a qualitative evaluation by the Review Team members; a simple "yes" or "no" to each such point is often not sufficient for the report. The rationale for qualitative judgement should be explained in sufficient detail so that others can understand its basis.

Safety assessment plans for authorizations and inspections, as well as investigations, may be used to supplement or in place of some of the detailed questions in checklists as they apply to specific practices (see Ref. [1]).

5.2. Qualitative information

Inevitably, many of the questions that will be asked in assessing the effectiveness of a regulatory programme for radiation safety will result in a qualitative response. Even quantitative information, such as operational data, often requires qualitative interpretations. The quality of such interpretation will generally depend upon the experience and understanding of Review Team members.

5.3. Quantitative information

Provided that quantitative information is interpreted with care and understanding, it can form an invaluable part of the assessment by the Review Team members.

To be effective, a regulatory programme for radiation safety requires a records maintenance system in which information is clear, up to date and readily retrievable. In general, the information should cover all the operational aspects of the regulatory programme areas.

5.4. Performance criteria

Many of the performance indicators require criteria against which regulatory programme development and effectiveness can be judged. The primary performance criteria in the principal areas of evaluation (see paragraph 3.1) against which performance indicators can be compared are:

1. ***Laws*/regulations and Regulatory Authority**
   The laws provide effective empowerment to the Regulatory Authority, the regulations implement the BSS and the Regulatory Authority applies a systematic approach to the fulfilment of its responsibilities.

2. **Notification**
   The inventory established through the notification system (including notification through application for authorization) can be used to effectively identify radiation sources subject to regulatory control and their location.

3. **Authorization(licensing/registration)**
   The authorization system functions so that radiation source practices are likely to be safe and in compliance with regulatory requirements.

4. **Inspection**
The Regulatory Authority has an established and effectively functioning inspection programme.

5. **Enforcement**
The Regulatory Authority makes use of its enforcement powers, and these enforcement powers are effective in obtaining compliance with regulatory requirements.

6. **Emergency response**
The Regulatory Authority is prepared for, and functions effectively in, emergency situations, preferably within a national system of emergency response.

7. **Investigations and follow-up**
Effective investigation of situations that have actual or potential radiological consequences can be conducted, and there are effective mechanisms to learn from such situations and to take appropriate measures to prevent recurrence.

8. ***Technical services***
Appropriate and effective technical services are available to both the users of radiation sources and the Regulatory Authority.

9. ***Co-ordination and co-operation***
The necessary co-ordination and co-operation between the Regulatory Authority and other organizations is effective, assuming that no single organization will be able to address all matters associated with radiation protection and safety of radiation sources.

10. **Staffing and training**
The Regulatory Authority has an adequate number of appropriately qualified staff and a training programme for staff.

11. **Funding**
Adequate resources are available and utilized to enable the Regulatory Authority to operate effectively and perform all of its functions.

12. **Information dissemination**
The Regulatory Authority has an effective mechanism to rapidly disseminate warnings and information in the event of an accident, and to ensure that relevant information having an important bearing on operational radiation protection and source safety is collected, evaluated and periodically disseminated to all who need or wish to know.

Additional and/or more detailed performance criteria can be derived from Refs [1–3].

The assessment process of the effectiveness of a regulatory programme for radiation safety described in this section and in Section 6 is depicted in Fig. 1.

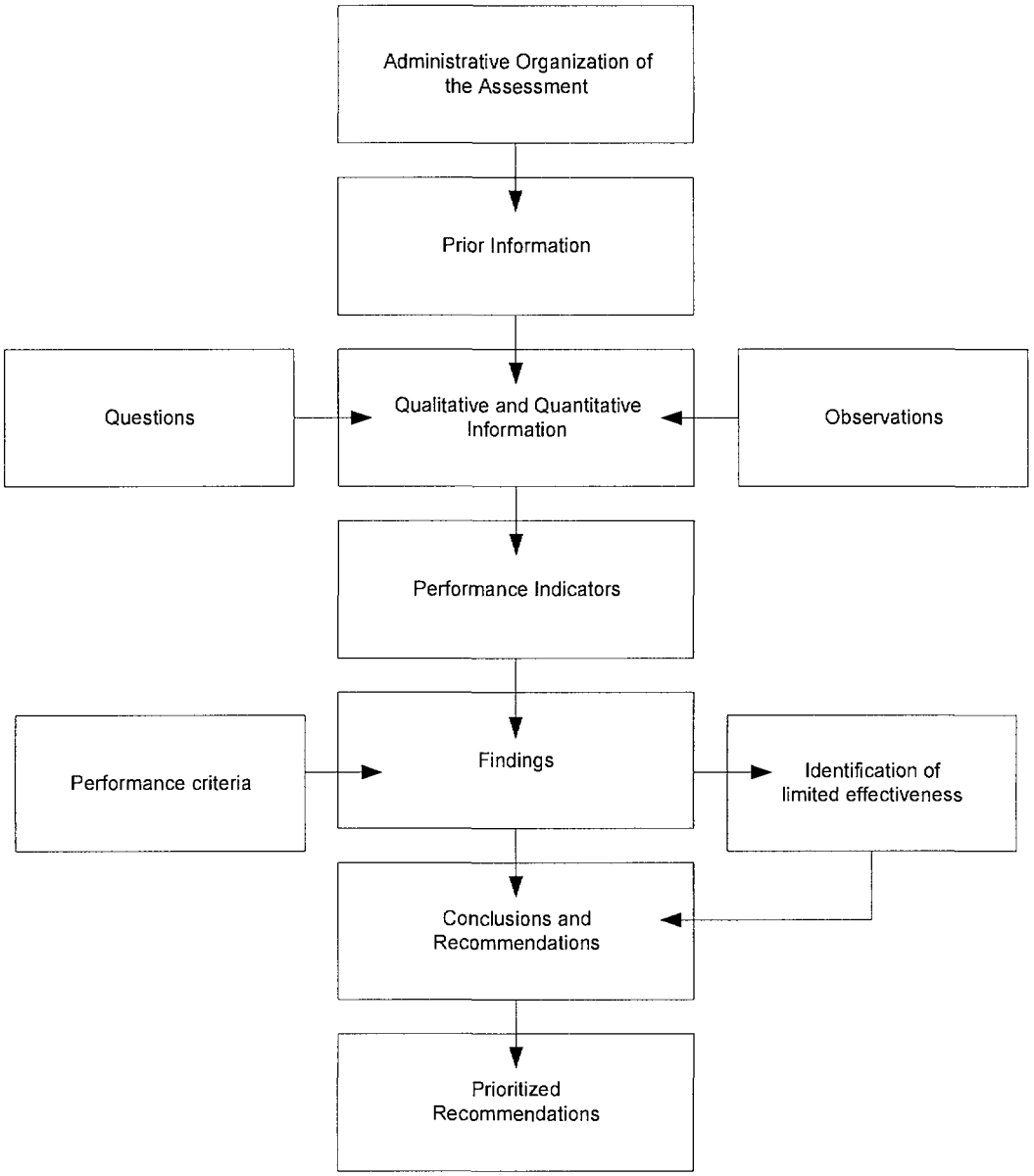

FIG. 1. The assessment process.

6. CHARACTERIZATION OF THE ASSESSMENT FINDINGS

It is inevitable that some parts of the regulatory programme for radiation safety will appear to fully meet performance criteria while others will benefit from improvements of either a major or minor nature. Major objectives of an assessment are to identify problem areas that limit, or have the potential to limit effectiveness; to determine the causes of such problem areas; and to make appropriate recommendations for improvement. The value of an assessment lies in the improved programme effectiveness arising directly out of implementation of the resulting recommendations. Depending on the number and breadth of recommendations, there may be immediate resource implications that impede their implementation. In such cases, the Review Team should address whether some areas of the regulatory programme for radiation safety might be scaled back to enable funding the implementation of higher priority recommendations.

6.1. Conclusions and recommendations

A conclusion about the degree of overall effectiveness of the regulatory programme for radiation safety tends to be a very subjective matter which is best avoided. Rather the degree of effectiveness can be implied by identification of the strengths and weakness of the programme areas evaluated. Certain specific areas of the regulatory programme for radiation safety, however, must be regarded as mandatory, i.e., the first six areas listed in paragraph 3.1. If one of these areas is not adequate when the Regulatory Authority considers its programme to be operational, or several are marginally adequate, then a conclusion that the regulatory programme for radiation safety is not sufficiently effective might be justified. A relatively objective view can be taken of the need, the wording and the priority assigned to each of the individual recommendations that arise out of conclusions about areas of limited effectiveness.

6.2. Prioritization of recommendations

The Review Team should consider the actual or potential consequences arising from each identified area of limited effectiveness, and reflect this in the prioritization of the associated recommendations. Suggested priority categories are:

1. **Essential,** meaning that a delay in implementation could result in a substantial and immediate hazard to health, and/or that the recommendation addresses a serious deficiency in the regulatory programme for radiation safety.
2. **Important**, meaning that until the situation is corrected, regulatory programme effectiveness in a certain area is significantly compromised.
3. **Advised,** meaning that the recommendation identifies a relatively minor deficiency in regulatory programme effectiveness.

This system of prioritization is coupled to the following guidelines for the timing of implementation:

Priority	**Timing of implementation**
Essential	Should be immediate, certainly without undue delay.
Important	Should be as soon as can be reasonably achieved.
Advised	Implementation enhances effectiveness but may be delayed.

Such a scheme for prioritization places certain restraints on the Review Team, and the following guidelines may be of assistance:

(i) The **'Essential'** priority should be carefully restricted to urgent matters that clearly require immediate attention. Review Team members should always be aware that unnecessary use of this priority will inevitably devalue its impact, and could also lead to a less than optimised use of available resources.
(ii) Many of the recommendations might be expected to concern relatively routine matters. The majority of these should be prioritized as **'Important'**, so that they will be addressed, but without undue urgency or programme disruption.
(iii) The **'Advised'** priority should be reserved for recommendations that should not create undue concern, even if implementation is delayed or overlooked for some considerable time.

APPENDIX I
QUESTIONS LEADING TO PERFORMANCE INDICATORS

The questions in this appendix are not intended necessarily to imply requirements for the regulatory programme nor do negative answers necessarily indicate problems. Many questions are concerned only with good practice. Other questions are simply intended to extract information from the Regulatory Authority on the status and performance of the regulatory programme for radiation safety. In some cases, the questions are based on requirements in the BSS. The Review Team should analyse the responses to the questions, and form its own conclusions.

A pre-requisite to a peer review is a full understanding of the functions and structure of the Regulatory Authority(ies) and it is what the Review Team should intent to establish first and this Appendix provides an initial set of questions that the Review Team may use as guidance for such purpose. The Review Team can and should ask additional questions of the Regulatory Authority, whenever needed, in order to: (1) adapt the assessment to the status of the regulatory programme development and the specific issues facing the Regulatory Authority, (2) obtain more detailed information about any of the principal areas of evaluation, (3) obtain more focused information on the causes of potential problems that limit, or have the potential to limit, regulatory programme effectiveness, and (4) support any potential recommendations by the Review Team.

I-1. *Laws*/regulations and Regulatory Authority

(a) Is a Regulatory Authority established by the Government and empowered to authorize and inspect regulated activities and to enforce the laws, regulations and other regulatory requirements (e.g. technical prescriptions attached to licence)?

(b) Is the Regulatory Authority able to fulfil its legislative mandate under the enabling provisions of the legislation pertaining to radiation protection and safety (e.g. does it have the resources, does the mandate cover all radiation source practices, do the Regulatory Authority's functions cover all aspects of regulatory control — notification, authorization, inspection and enforcement)?

(c) Is the Regulatory Authority established as a body that is effectively independent of Government organizations that are responsible for the promotion and development of the practices being regulated?

(d) Is the Regulatory Authority established as a body that is effectively independent of registrants, licensees and the designers and constructors of the radiation sources used in practices?

(e) Does the Regulatory Authority have a plan and schedule to develop regulations and prescriptive requirements/practice-specific guidance?

(f) Have regulations been promulgated based on the BSS and the International Atomic Energy Agency's (IAEA) regulations for the safe transport of radioactive material?

(g) Do the laws/regulations adequately define their scope and provide for exemption in accordance with the BSS requirements?

(h) Does the Regulatory Authority revise and update regulations and guidance as needed, based on the Regulatory Authority staff's experience with applications for authorization, inspection results, enforcement results, investigation findings, as well as on international recommendations for radiation protection and safety?

(i) Do the regulations fully implement the BSS requirements regarding the safety and security of radiation sources?

(j) Do the regulations fully implement the BSS requirements relating to occupational, public and patient protection?

(k) Does the Regulatory Authority have access to information on doses to workers in all practices covered by the regulations and, when appropriate, on discharges to the environment?

(l) Has the Regulatory Authority established procedures, including those for quality assurance and analysis of programme data, to ensure that it maintains an effective regulatory programme for radiation protection and safety of radiation sources?

(m) Is the Regulatory Authority self-sufficient in specialist expertise? If not, does it have available expert advisers and/or advisory committees?

I-2. Notification[5]

(a) Has the Regulatory Authority prioritized the need for gaining regulatory control over sources and practices in terms of the likelihood and magnitude of potential exposures, as evidenced by a documented priority list and a documented explanation of the bases/rationale for the prioritization?

(b) Has the Regulatory Authority identified and listed likely source users (both past and present) within the State? If 'yes', indicate whether the basis for the listing is specified.

(c) Has the Regulatory Authority informed likely source users of the requirement for notification?

(d) Has the Regulatory Authority followed up (commensurate with the risk of the radiation source or practice) by further attempts to contact likely source users by telephone or by on-site visits, or to locate potentially abandoned sources when there was no response to the requests for notification?

(e) Has the Regulatory Authority followed up (commensurate with the risk of the radiation source or practice) on cases where the reply to the request for notification

[5] Questions (a) through (e) relating to notification are mainly oriented toward the organizational and implementation phases of a regulatory programme for radiation safety when the Regulatory Authority is attempting to gain regulatory control over sources and practices. They are directly related to the issue of whether or not the Regulatory Authority has established an effective inventory of radiation sources and source users.

was negative, but where the Regulatory Authority has contradictory information or other reasons to believe that the respondent may possess sources?

(f) Does the Regulatory Authority document and log into an inventory, as appropriate, identified radiation sources (in use, in storage, or abandoned) and source users?

(g) Does the Regulatory Authority periodically update the radiation source user and source inventory[6]?

(h) Has the Regulatory Authority developed and implemented a process to check on the accuracy of the notification/inventory system, with an emphasis on radiation sources or practices with higher risks?

(i) Can the Regulatory Authority identify and locate radiation sources (either directly through its own inventory or through authorized users' inventories) subject to its regulatory control?

I-3. Authorization (licensing/registration)

(a) Does the Regulatory Authority inform radiation users of requirements to submit an application for authorization within a certain time period[7]?

(b) Has the Regulatory Authority established and published criteria for establishing the level (registration or licensing) of authorization required for given radiation practices/sources?

(c) Does the Regulatory Authority provide application forms and guidance for authorization to applicants?

(d) Has the Regulatory Authority established priorities for reviewing applications for authorization (licensing/registration)?

(e) Does the Regulatory Authority provide timely, clear and complete requests to radiation users for information that is omitted from, or that needs to be clarified, in applications for authorizations?

(f) Has the Regulatory Authority developed or adopted guidance (e.g. IAEA guidance in Ref. [1]) for the assessment of applications? Is such guidance available to applicants and Regulatory Authority technical staff?

(g) Does the assessment of completed authorizations indicate that:

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[6] The RAIS or a similar data system for source accountability needs to be kept up to date from the time it is initiated.

[7] This applies to the early stages of regulatory programme development (i.e., organizational and implementation phases), where those in possession of radiation sources have submitted a notification only. When operational, the regulations should not allow anyone to possess a source before meeting applicable authorization requirements.

- applicable guidance documents (e.g. safety assessment plans) are followed, inspection history is reviewed, and radiation protection and safety issues are properly addressed?

- authorization documents clearly indicate what is authorized (e.g. use, maintenance, release, transfer, possession, disposal) and what requirements the authorized radiation user must meet?

- conditions/requirements specified in the authorization are appropriate?

- the assessment process is adequately documented (e.g. does it include the authorized user's complete application, the safety analysis or other basis for granting the authorization, and the final authorization)?

- the assessment process is completed in a timely manner, from initial receipt of the application to final issuance of the authorization?

(h) Does the Regulatory Authority have a listing/register of authorizations, by category of practice[8]?

(i) Does the Regulatory Authority request from authorized radiation users, periodic reports related to radiation protection and safety in the facilities?

(j) Has the Regulatory Authority established its lines of communication with senior management of authorized practices/sources?

I-4. Inspection

(a) Has the Regulatory Authority established inspection priorities, frequencies, and schedules:

- in relation to hazard associated with practices?

- in consideration of past performance, as evidenced by inspection history?

(b) Are appropriate procedural and technical guidance documents available to Inspectors and followed during the course of the inspections?

(c) Do Review Team member observations of: (1) the Regulatory Authority's staff during inspections, (2) completed inspection documentation, and (3) records of management observation of Inspectors performance at radiation user sites, indicate that:

- inspections address significant radiation protection and safety issues and any additional issues regarding compliance with regulatory requirements?

- inspections address previously identified safety and non-compliance issues which have not yet been completely resolved by the authorized radiation user?

[8] Such as the RAIS or a similar data system.

(d) Is the Regulatory Authority's inspection documentation clear?

(e) Is the inspection documentation consistent with guidance on the preparation of inspection reports?

(f) Are radiation protection and safety issues and matters of non-compliance thoroughly addressed in the inspection documentation?

(g) Are inspection findings communicated to the radiation user in a timely and clear manner?

(h) Are inspection findings communicated in a timely and clear manner to appropriate members of the Regulatory Authority staff (e.g. staff responsible for authorization and enforcement)?

(i) Is there documented follow-up in response to regulatory non-compliance identified?

(j) In cases of substantial violations of radiation protection and safety requirements, are follow-up inspections conducted to determine that corrective actions have been taken and are adequate?

(k) Are inspections of authorized radiation users in high priority categories conducted within established frequencies, except when the Regulatory Authority documents its reasons for not doing so?

(l) Is there a database derived from inspection reports by which trends in non-compliance or degraded radiation safety can be analysed?

(m) Does the Regulatory Authority review on a regular basis the data on occupational exposures in all practices covered by the regulations in order to identify any underlyning trends?

(n) Are such analyses conducted and appropriate actions taken on findings?

I-5. Enforcement

(a) Has the Regulatory Authority established enforcement policy/guidance?

(b) Are the enforcement actions being applied consistently and objectively from one authorized radiation user to another and in accordance with enforcement policy/guidance?

(c) Is there appropriate interaction between the Regulatory Authority authorization and inspection staffs regarding the nature of the enforcement action based on inspection findings?

(d) Do inspection findings lead to timely enforcement actions, consistent with the nature of the radiation risks involved?

(e) Does enforcement correspondence from the Regulatory Authority require a response from an authorized radiation user to indicate that the required corrective actions have been taken and, does the correspondence clearly state: (1) the nature of the problems to be addressed, (2) what is expected of the radiation users in the response, and (3) the timing for the radiation user's response?

(f) Does the Regulatory Authority appropriately evaluate the authorized radiation user's corrective actions in response to the enforcement action?

(g) Is the Regulatory Authority generally successful in sustaining/defending challenges to its enforcement actions?

(h) Has the Regulatory Authority established criteria for the application of sanctions, if appropriate, in cases of non-compliance?

I-6. Emergency response[9]

(a) Are the role and functions of the Regulatory Authority for emergency management defined and documented, including interaction with authorized radiation users in the event of an on-site emergency?

(b) Is there a national emergency management plan which defines and co-ordinates the emergency response of various national and local organizations having a role in emergency response? If so, is the Regulatory Authority's plan integrated into the national plan?

(c) Has the Regulatory Authority established and issued guidance or regulations for radiation users on reporting accidents and other situations involving actual or potential radiological consequences (e.g. information needed, timeliness, method of reporting)?

(d) Does the Regulatory Authority have procedures, training programmes, equipment, facilities and logistic support to implement its role and functions in emergency response?

(e) Are actions levels established?

(f) With respect to the more severe types of accidents that can be reasonably anticipated and which are within the scope of the Regulatory Authority's role for emergency response, are periodic and appropriate exercises conducted to:

- assess the effectiveness and adequacy of the Regulatory Authority's emergency response plan and procedures?

- ensure that emergency response capabilities remain effective?

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[9] Further checklists are provided in IAEA-TECDOC-953, "*Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accidents*" (1997).

(g) Are the Regulatory Authority's emergency response plans adjusted or modified as a consequence of performance evaluations following exercises?

I-7. Investigation and follow-up

(a) Has the Regulatory Authority established investigation levels, particularly in terms to doses to workers, above which investigation into the causes should be conducted?

(b) Has the Regulatory Authority established procedures for investigation of accidents, including documentation and follow-up procedures?

(c) Does the Regulatory Authority respond in a timely and appropriate manner to accidents and other situations requiring investigation in accordance with established procedures?

(d) Is the Regulatory Authority's level of effort on investigation and follow-up usually commensurate with the potential health and safety significance?

(e) Are findings from the investigation and follow-up documented in accordance with established procedures?

(f) Does the Regulatory Authority take appropriate corrective and/or enforcement actions based on findings from investigation and follow-up?

(g) Does the Regulatory Authority verify the effectiveness of subsequent corrective and/or enforcement actions following its investigation?

(h) Are the causes and consequences of accidents analysed for "lessons learned" and is information regarding such situations (including causes, consequences, and preventive/mitigation actions) disseminated in accordance with established procedures?

(i) Does the Regulatory Authority participate in international reporting and dissemination systems/programmes, including dissemination of information within the State about accidents and similar matters in other countries?

I-8. *Technical services*[10]

(a) Are the following essential technical services available within the State, to both the Regulatory Authority and authorized radiation users, or are otherwise available through arrangements from outside the State:

- dosimetry services: (1) for the assessment, as appropriate, of external and internal doses for the types of radiation practices authorized by the Regulatory Authority; and (2) that have their accuracy verified (e.g. accredited) by either the Regulatory Authority or an acceptable third-party organization?

[10] This list of technical services are the principal kinds needed in most States. Additional technical services might also be needed in some States.

- laboratory services, with qualitative and quantitative analysis capability, for radiation measurements, commensurate with the needs for radiation safety in the country?

- calibration services, traceable to a standard dosimetry laboratory, for calibration of radiation detection equipment and medical radiation devices, as appropriate?

- radioactive waste management facilities for long term storage and/or disposal, as may be appropriate for the types of practices authorized by the Regulatory Authority, or are otherwise available through arrangements outside the State?

- training services, commensurate with the scope of the regulatory programme for radiation safety and the needs of users of radiation sources?

- expert technical assistance to supplement both the Regulatory Authority staff and radiation user capabilities?

I-9. ***Co-ordination and co-operation***

(a) Has the Regulatory Authority made an appropriate effort to identify areas where co-ordination and co-operation with other organizations are needed to fulfil its mandate (e.g. the customs service and organizations responsible for emergency intervention, transportation of hazardous materials, public health)?

(b) Where there is a need for co-ordination/co-operation, have the Regulatory Authority and the other organizations adopted and implemented appropriate procedures?

(c) Does the Regulatory Authority have a specific arrangement with the national customs or similar organization to prevent unauthorized import of radiation sources into the country? Has this arrangement been demonstrated to work (e.g. by detecting unauthorized imports)?

(d) Does the Regulatory Authority have specific arrangements for co-ordination and co-operation on an international level, such as bilateral and multilateral agreements?

I-10. Staffing and training

(a) Are the Regulatory Authority's staffing plans, staff qualification requirements and individual training plans in place, appropriate, and funded?

(b) Does the Regulatory Authority have sufficient numbers and appropriately qualified staff, and an appropriate training programme? [To be judged against the Regulatory Authority's performance with authorization assessments, inspections, enforcement activities, investigations, and emergency response.]

(c) Is the Regulatory Authority's staff turnover rate adversely affected by compensation, lack of professional satisfaction, or management practices?

I-11. Funding

(a) Is the Regulatory Authority's funding independent of income from authorization and inspection activities, and enforcement fines?

(b) Are the Regulatory Authority's resources adequate to perform its functions?

(c) Are the Regulatory Authority's facilities and equipment (e.g. the work spaces, laboratories, radiation detection equipment, personal protective equipment, work-related transportation, information technology equipment) adequate for its tasks? [To be judged against Regulatory Authority's performance with authorization reviews, inspections, enforcement activities, investigations, and emergency response.]

I-12. Information dissemination

(a) Has the Regulatory Authority established and implemented procedures for the collection of national and international information having an important bearing on operational radiation protection and safety as related to practices authorized by the Regulatory Authority, and for the periodic dissemination of such information to relevant authorized users, manufacturers, suppliers, international organizations, etc.?

(b) Has the Regulatory Authority established and implemented procedures for rapid dissemination of information in the wake of an actual or potential accident?

(c) Has the Regulatory Authority established and implemented procedures for making available relevant information (e.g. about radiation protection and safety, and other matters concerning the regulatory programme for radiation safety) to interested or affected members of the public?

APPENDIX II
INFORMATION IN ADVANCE FOR THE ON-SITE ASSESSMENT

The following list provides examples of the types of information that the Review Team might request in advance for the on-site assessment. [The list is provided only as guidance, and the Review Team may expand or reduce the list, as appropriate.]

- Copies of the relevant laws and regulations.
- Organizational chart, staffing plan, and a description of the structure and functions of the Regulatory Authority.
- Description of the Regulatory Authority's scope of activities in each of the principal areas of evaluation.
- Readily available statistical data and/or performance information concerning the status of Regulatory Authority activities.
- Number of authorized radiation users.
- Listing of the types/categories of authorized practices.
- Identification of the technical services available to the Regulatory Authority and radiation users.
- Copies of agreements (e.g. Memoranda of Understanding) between the Regulatory Authority and other organizations.
- Copies of previous internal or external audits of the Regulatory Authority.
- Listing or description of significant investigations conducted by the Regulatory Authority.
- Copies of application forms and other guidance regarding authorization, inspection, etc.
- Description of the Regulatory Authority's training programme.

APPENDIX III
CHECKLISTS TO ASSIST IN THE ASSESSMENT OF REGULATORY STAFF PERFORMANCE

Four examples of checklists are provided in this appendix. Checklists could be formulated for other areas of the regulatory programme for radiation safety. Also, other formats of checklists could be used. Checklists are a tool which facilitates the collection of Regulatory Authority information and the preparation of the assessment report, but could also narrow the attention to the points on the checklist only. The utility and use of checklists, therefore, has to be decided by the Review Team on a case by case basis.

III-1. Checklist for review of authorization[11] files

1. Name of Regulatory Authority

2. Authorization reviewer name(s)

3. Authorized user/licensee/registrant name or title (the user)

4. User location

5. Type of practice

6. Type of authorization action (check one or more)
   - New authorization
   - Authorization renewal
   - Authorization amendment
   - Authorization termination

7. Date that the initial application for authorization was received

8. Date(s) of any letters to the user requesting further information from the Regulatory Authority regarding the application

9. Date of final action on the application for authorization by the Regulatory Authority

10. Are the initial application and all letters to the user requesting further information from the Regulatory Authority included in the Authorization File?

11. Are there safety assessment plans for the authorization for the most common types of practices? (see Ref. [1]). If so, were they followed in the review of the applications?

12. If appropriate or as otherwise indicated by following a safety assessment plan for authorization, do documents (e.g. a license and/or user application) in the Authorization File include, identify and/or address:

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[11] *The term "authorization" is used here synonymously for actions or activities associated with* registration and/or licensing by the Regulatory Authority.

- user management signature and date on the application?
- nature of radiation sources authorized?
- physical/chemical form of radioisotopes authorized?
- quantities of radioisotopes authorized?
- nature of authorized practices/uses?
- places/locations of use, including temporary sites?
- the Radiation Protection Officer and his/her hierarchic position in the organization?
- duties/responsibilities of the Radiation Protection Officer?
- qualifications and training of staff conducting radiation source operations?
- supervision of staff?
- monitoring instruments/equipment?
- calibration of monitoring instruments/equipment?
- identification by make and model of sealed sources and/or devices?
- leak test procedures?
- maintenance/service procedures?
- health surveillance?
- personnel dose monitoring (external and internal)?
- routine operating procedures?
- emergency procedures/plans?
- fire protection?
- security of sources?
- access control?
- shielding?
- radiation resistance of material?
- cautionary posting/labelling practices?
- radiation safety instructions?
- radioactive material procurement/acquisition/receipt procedures?
- inventory control?
- transportation of radioactive material?
- waste management/disposal practices?
- releases to the environment?
- special authorizations or exemptions from specific regulatory requirements?
- workplace/environmental survey and monitoring programme?
- internal audits/self assessments?
- financial assurance requirements (for decommissioning), if applicable?
- quality assurance/quality control?
- ALARA practices/programme and investigation levels?

13. Authorization process
    - Are all deficiencies (if any) in the application clearly stated in a letter or otherwise communicated to the applicant?
    - Is the applicant's response to deficiencies noted in the original application adequate, or followed up for further clarification?
    - If a visit is conducted by the Regulatory Authority to the applicant's site during the authorization process, is it documented?
    - Do the Regulatory Authority staff consider the applicant's inspection/compliance history, if any, when reviewing the application?
    - Is there supervisory review of the completed staff analysis before issuance of an authorization?

14. Does the authorization document (i.e. license or registration) contain the following information:
    - radiation sources authorized?
    - authorized users?
    - conditions12 for authorized uses?
    - limitations on authorized uses13?
    - special (non-standard) conditions, if needed?
    - conditions tying the authorization to commitments in the application?
    - citations to applicable regulations?
    - expiration date?
    - signature of Regulatory Authority official, and date?

15. Terminated authorizations
    - Did the user dispose or transfer its radiation sources in an acceptable method by:
        - transfer to another authorized user?
        - transfer to an authorized location in another State (e.g. export)?
        - return to manufacturer?
        - shipment to an authorized storage/disposal site?
    - If the authorized material was a sealed radioisotope source or a device containing a sealed source, was a final leak test performed?
    - Did the user verify that the recipient to whom the radiation source was transferred was authorized to receive it?
    - If the radiation source was transferred, did the user verify receipt by the consignee?
    - Was a close-out survey, if applicable, for radioactive contamination performed at the location of radiation source use? If so, does the authorization file include documentation on:
        - the manufacturer, model number, serial number, and calibration date of the radiation instruments used for the close-out survey?
        - the date(s) of the close-out survey?
        - identification of the person making the survey?
        - all radiation/radioactivity measurements, including background levels?
    - Did the Regulatory Authority perform a termination inspection, and properly document such an inspection?
    - If the Regulatory Authority performed a termination inspection, were radiation measurements made and documented?

16. Authorization files
    - Are the files complete and orderly?
    - Do the files include the application, requests for further information or clarification and the replies, and all amendments/changes to the authorization?

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[12] The use of the term "conditions" here means relevant special requirements which are not explicitly stated in the regulations but are specified on the license or registration document, e.g. authorized personnel, requirements for replacing ageing equipment or components of ageing equipment.

[13] Authorized users of certain types of equipment (e.g. teletherapy, product irradiators) are often limited on the types of maintenance and other activities they can perform, and are required to obtain the services of persons who are specifically authorized by the Regulatory Authority to perform such activities.

- Do the files include the Regulatory Authority's staff review methodology (e.g. checklists, safety analyses, references to regulations, safety assessment plans) for reviewing and the basis for approving the requested action?

17. Did a Review Team member meet with the Regulatory Authority staff who assessed the application and describe the results of the assessment for this action?

III-2. Checklist for a review of inspection techniques

Before the inspection, explain to the Inspector(s) the extent of the Review Team-member's participation in the inspection, how to introduce the Review Team member(s) to the licensee or registrant, and the method to be followed in evaluating the Inspector's performance.

1. Date of inspection

2. Inspector name(s)

3. Authorized user/licensee/registrant name or title (the user)

4. Type of practice

5. Type of inspection (e.g. routine, accident follow-up, other type of special inspection)

6. Inspector preparation
   - Was there an adequate review of the authorization and compliance history?
   - Was the Inspector appropriately equipped with radiation detection instruments? Were they calibrated?
   - Did the Inspector have other supplemental materials, that might be needed or useful? (e.g. forms, regulations, identification, dosimetry, personal protective equipment)

7. Entrance interview
   - Was the interview conducted at the appropriate user management level?
   - Was the purpose, scope, and method of the inspection explained?

8. Inspection content/observations
   - Did the Inspector:
     - use an appropriate form, if applicable and/or a safety assessment plan for the inspection, if available?
     - tour the facility and check on conditions of source use?
     - check operating procedures for adequacy and use?
     - check for proper posting/labelling?
     - verify security of radioactive material/sources?
     - check workers for personnel dosimetry devices?
     - interview authorized users/monitored personnel?
     - interview ancillary workers (e.g. janitors, nurses, assistants, etc.)?
     - take dose rate measurements?
     - take samples/wipes for radioactive contamination, if applicable?
     - evaluate ALARA practices?
     - review past accidents, and overexposures?

- Was the inspection conducted in sufficient depth and scope?
- Did the Inspector verify corrections to previously noted items of non-compliance or poor safety conditions?

9. Record verification
   - Did the Inspector review user records and verify them against the information obtained from interviews and observations for the following, if applicable:
     - radioactive source procurement/acquisition/receipt?
     - inventory of authorized radiation sources?
     - transfer of authorized radiation sources?
     - user internal audits/self assessments?
     - surveys and monitoring?
     - personnel dose monitoring (external and internal)?
     - qualification/training and retraining of personnel?
     - emergency plans?
     - instrument calibration?
     - source utilization logs?
     - leak tests of sealed sources?
     - waste management/disposal practices?
     - releases to the environment?
     - quality assurance/quality control?
     - maintenance?
     - accidents?

10. Inspector's professionalism
    - Did the Inspector use proper health physics techniques (e.g. self monitoring)?
    - Was the Inspector sufficiently knowledgeable about the applicable regulations and the practice being inspected?
    - Was the Inspector sufficiently knowledgeable about good radiation protection and safety practices?
    - Did the Inspector ask appropriate questions?
    - Did the Inspector demonstrate suitable rapport with managers and workers?

11. Exit interview
    - Did the Inspector prepare for the exit interview and assemble appropriate material, if needed, in advance?
    - Was the exit interview conducted at the appropriate management level?
    - Were items of non-compliance completely explained?
    - Did the Inspector make any other recommendations, not related to compliance?
    - Did the Inspector explain the reporting/follow-up process?
    - If applicable, did the Inspector explain the enforcement process?

12. Inspection follow-up (subsequent to visit)
    - Did the Inspector properly document the inspection?
    - Did the Inspector describe the inspection results to Regulatory Authority management?
    - If needed, did the Inspector communicate or co-ordinate the information obtained from the inspection with other Regulatory Authority staff (e.g. authorization and enforcement staffs)?

13. Summary of the Review Team-member assessment for the Inspector
    - Provide short description of findings.
    - Was the inspection sufficient to identify critical health and safety issues?
    - Is improvement or training needed? If so, in which areas?
    - Was the assessment discussed with the Inspector?

III-3. Checklist for a review of inspection reports

1. Name of Regulatory Authority

2. Inspector name(s)

3. Authorized user/licensee/registrant name or title (the user)

4. User location

5. Type of practice

6. Inspection date(s)

7. Names and position of responsible person(s) seen during the inspection

8. Type of inspection (e.g. routine, accident follow-up, other type of special inspection)

9. Frequency of routine inspection for this type of practice

10. Was the inspection announced in advance to the user?

11. Did the inspection cover the entire authorized program, or only portions of it? If it was a partial inspection, what portions were inspected?

12. Previous inspection (i.e. information regarding the inspection prior to the most recent one):
    - Date of previous inspection
    - Date of transmittal of previous inspection findings to the user
    - Date of user response, if any, to the previous inspection findings
    - Date previous inspection findings closed

13. Does the report for the most recent inspection cover:
    - closure of previous items of non-compliance?
    - review or closure of previous accidents/overexposures?
    - an exit meeting, with an appropriate level of management?
    - identification of operations that were inspected?
    - interviews with the monitored personnel?
    - interviews with ancillary workers (e.g. janitors, nurses, assistants)?
    - radiation levels measured by the Inspector, if applicable?
    - results of sampling for radioactive contamination taken by the Inspector, if applicable?

14. Does the inspection report indicate that the Inspector checked, if applicable or as otherwise indicated by use of a safety assessment plan:
    - condition of facilities and equipment?
    - ALARA practices/programme, e.g. investigation levels, internal audits/self-assessments?
    - operating procedures?
    - emergency plans/procedures?
    - accident documents?
    - training programme?
    - radiation detection instruments/equipment/records?
    - instrument calibration?
    - posting/labelling?
    - security of radiation sources?
    - radiation source procurement/acquisition/receipt?
    - types and uses of radiation sources against terms of the authorization?
    - user's source inventory against records of receipt, transfer and disposal?
    - surveys and monitoring?
    - personnel dose monitoring (external and internal)?
    - protective clothing?
    - ventilation/fume hoods?
    - position, emergency stops, access control?
    - warning systems (signals, designated areas)?
    - leak tests?
    - maintenance/repair/modification of facilities?
    - waste management/disposal practices?
    - releases to the environment?
    - quality assurance/quality control (e.g. internal audits or self assessments records)?
    - practices at field sites/temporary job sites (e.g. radiographers)?
    - were the items covered appropriate for the type of use and the stated scope of the inspection?

15. Inspection results
    - Is the report complete, and in an appropriate format?
    - Does the report clearly indicate the items of non-compliance and the basis for such determinations?
    - Does the report indicate any other recommendations to the user which are not related to compliance?
    - Was an exit meeting conducted at the appropriate management level?
    - Does the report indicate communication or co-ordination of the information obtained from the inspection with other Regulatory Authority staff (e.g. authorization and enforcement staffs, inspection supervisor)?

16. Inspection follow-up/enforcement (when applicable)
    - Was the user cited for items of non-compliance?
    - Were the citations clear, complete, and timely?
    - Were repeat items of non-compliance considered in formulating the enforcement action?
    - Did the user respond to the citations?
    - Was the user's response evaluated by appropriate Regulatory Authority staff?

- Was the user's response followed up by the Regulatory Authority in a suitable manner?
- Was the enforcement action/follow-up appropriate?

17. Inspection/Compliance files (may be included in a single file with the authorization)
    - Is the inspection/compliance file orderly and complete?
    - Is information about user accidents or other matters related to degraded safety included in the inspection/compliance file, or appropriately cross-referenced?
    - Is there adequate supervisory review of the inspection reports, letters, and user responses?

18. Did the Review Team member meet with the inspector to describe the results of the assessment for this inspection report?

III-4. Checklist for a review of investigation reports

1. Name of Regulatory Authority
2. Name of regulatory staff/accident responder(s)/investigator(s)
3. Authorized user/licensee/registrant name or title (the user)
4. User location
5. Type of practice
6. Date of accident
7. Location of accident
8. Date/Time that Regulatory Authority was first contacted about the accident?
9. Date/Time of Regulatory Authority's investigation, if any?
10. Nature of situation subject to investigation
    - Above the relevant investigation levels?
    - Exposure above the relevant dose limits?
    - Release of radioactive material?
    - Orphan sources[14] ?
    - Sources illegally imported into the country?
    - Contamination event?
    - Loss of control?
    - Damage to equipment or facility?
    - Equipment or procedure failure?
    - Leaking radioisotope source?
    - Transportation accident?
    - Incorrect administration of medical dose?
    - Other? (describe)

[14] Orphan sources: radiation sources that either were never subject to regulatory control or were subject to regulatory control but have been abandoned, or lost, or misplaced, or stolen or removed without authorization.

11. Type of investigation
    - On-site?
    - By telephone?
    - To be reviewed during the next inspection?
    - Other?
    - None?

12. Briefly describe what was being investigated.

13. Is the situation being investigated potentially generic (e.g. is it applicable to other users within the same practice, or using the same type of equipment)?

14. If it is a potentially generic problem area, did the Regulatory Authority disseminate relevant information as a result of the investigation to other users, suppliers, relevant international organizations, etc.?

15. Was closure of the investigation appropriate?

16. Does the investigation/follow up report indicate that:
    - the initial response by the Regulatory Authority was prompt?
    - the initial response by the Regulatory Authority was appropriate (e.g. for the degree of hazard presented by an accident)?

17. Does the investigation and follow-up file show that the investigation:
    - was performed with appropriate depth and scope?
    - was documented (e.g. reports, telephone conversation logs, calculations)?
    - resulted in appropriate regulatory actions (e.g. citations for non compliance with requirements, user restrictions, corrective requirements, dissemination of information)?
    - was monitored by management?

18. Was the investigation entered in the Regulatory Authority's database system?

19. Did the user provide a detailed report of the situation being investigated and corrective actions?[15] If so:
    - were the user report and corrective actions reviewed?
    - were the user report and corrective actions documented in the accident file?
    - was the accident and its follow-up reviewed during the next inspection?

20. Were the user report and the Regulatory Authority investigation report appropriately copied, cross-referenced, or filed in both the authorization and the inspection files?

21. Does the investigation report indicate whether the user met the Regulatory Authority reporting requirements?

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[15] Accidents often occur when a radiation source is being transported. Who provides a detailed accident/investigation report in such instances depends on national structures and laws, and might be the transporter, a government transport safety organization, the source owner/authorized user or the Regulatory Authority.

22. Does the investigation report include references to relevant public information?

23. Did the Review Team member(s) meet with the investigator(s) and manager(s) to describe the results of the assessment in this area?

APPENDIX IV
SUPPLEMENTAL GUIDANCE FOR ASSESSMENT DURING THE ORGANIZATIONAL PHASE OF A REGULATORY PROGRAMME FOR RADIATION SAFETY

1. **Laws/regulations**: The initial drafting of laws and/or regulations typically constitutes only a small portion of the total time lapse between initiation of drafting and final adoption by Government. The bulk of the time is consumed by review and negotiating details of the draft proposals with other Government bodies and the regulated community. This process often takes well over a year to complete, even in advanced nuclear countries. The Review Team should determine the status of the laws/regulations review and approval process, and attempt to identify any substantive issues which might be causing undue delay, or which could lead to compromising Regulatory Authority effectiveness.

   While the laws/regulations review and approval process is taking place, the initial cadre of the Regulatory Authority (or the group otherwise designated by Government to establish the regulatory programme) should be addressing other items listed in Section 3.2 to the extent practicable.

2. **Inventory of sources:** Even if a formal notification system is not yet in place, work should commence on establishing a national inventory of radiation sources. It should not be difficult to obtain a reasonable estimate of the size and scope of radiation source use to be regulated. Identification of the more hazardous sources, such as those used in hospital therapy units and product irradiators, should be relatively straightforward. Rough estimates of less hazardous sources, such as diagnostic X ray units in hospitals and clinics, and nuclear gauge uses in industry, can be established simply with some knowledge of the numbers and types of potential users. This preliminary inventory should be given a top priority since it is needed to serve as the basis for projecting resource requirements and technical support for the Regulatory Authority in addition to helping to identify those radiation sources which might require early regulatory attention for safety and security reasons. The team should assess the status of the inventory.

3. **Regulatory Authority staffing plan**: A staffing plan matches the types of skills, skill levels and the numbers of personnel in each category of skills with the types and size of practices to be regulated. During the organizational phase, it is anticipated that the Regulatory Authority will not have a staff in place to conduct a fully operational programme. A staffing plan at this stage is essential for budget recruitment, and training projections for a fully operational programme. The inventory of radiation sources can be used as a basis for the first iteration of the staffing plan. In order to credible, the plan should be realistic, taking into account the prevailing social and economic conditions in the country, and avoid being inflated. The plan should establish timing for orderly phasing of recruitment and training. There is some flexibility of the number and skill levels of staff depending on matters such as the structure of the regulations and use of guidance documents (see Ref. [3] for more details). The staffing plan should be considered as a living document subject to adjustments as experience is gained and to maintain compatibility with the size and scope of regulated practices. The Review Team should address the status of staffing plans during its assessment.

4. **Independence of the Regulatory Authority**: During the organizational phase of a regulatory programme for radiation safety, the Regulatory Authority staff is usually small. The Regulatory Authority is often very dependent on its parent of organization, or other Government organizations, for temporary use of their technical staff members and other

operating resources. This can be considered normal. As the Regulatory Authority progresses through the implementation phase toward the fully operational phase, however, this dependency for technical skills and operating resources can compromise the Regulatory Authority's "independent" decision making, particularly with respect to authorization, inspection and enforcement if allowed to continue unabated. The enabling legislation might reflect independence in theory, but the reality of the situation can be quite different. While appropriate legislation is necessary for independence, the long-rage staffing plan and provisions for funding can be indicators of how effective independence is to be achieved in practice.

Effective independence means independence of judgement and decision making as a Regulatory Authority, particularly with respect independence from those subject to its regulations and those involved with promotion of nuclear /radiation technologies. While the Regulatory Authority may be a component of a larger Government organization that may conduct regulated activities (e.g. a national health agency which operates hospitals), administrative channels, budget and staffing should be such that there are clear boundaries between the Regulatory Authority and those subject to regulation or involved in promotional activities.

During the organizational phase the team should evaluate those features of the regulatory programme for radiation safety which are necessary conditions for effective independence of the Regulatory Authority in the long-term, and distinguish them from those that can continue to provide unbiased technical services (e.g. a national dosimetry service, a national emergency co-ordinating service, and consultants with specialised technical skills). The Review Team should consider long-range plans of the Regulatory Authority to achieve an appropriate degree of independence if it is not already established.

5. **Co-ordination/co-operation with the national customs**: In conjunction with establishing its initial inventory of sources, the Regulatory Authority should also establish early co-ordination/co-operation links with customs to control further import of radiation sources. Import of less hazardous sources and replacement sources, such as those for hospital therapy units, might be allowed at the organizational phase with simple notification, while more hazardous sources for new initiatives might be delayed or held in storage until an appropriate safety assessment can be made and an authorization granted. The Review Team should assess how the acquisition of new radiation sources is being managed by the Regulatory Authority during the organizational phase.

6. **Technical library**: The Regulatory Authority should acquire a technical library, readily accessible to its staff, which contains guidance on the establishment and operation of a regulatory programme for radiation safety. The IAEA has produced a number of relevant documents which aid in the implementation of the BSS, such as guidance on regulatory infrastructure, assessment plans for authorization and inspection of specific practices, and practical protection and safety guidance for the more common types of practices. These IAEA documents or equivalent national documents are important for planning and organization of the regulatory infrastructure as well as the conduct of the more technical aspects of Regulatory Authority operations such as authorization and inspection. Many of the IAEA documents are provided to students in IAEA training courses and supplied to Governments through established channels, but that does not necessarily mean that they will be accessible to all within the Regulatory Authority who might find them useful. The Review Team should check the availability of appropriate technical documents during an assessment of the organizational phase.

ANNEX
INFORMATION AVAILABLE FROM THE REGULATORY AUTHORITY INFORMATION SYSTEM (RAIS)

RAIS is intended to provide information in the following areas:

- installations and radiation sources inventory;
- authorization process;
- inspection and follow up actions;
- dosimetry records of occupational exposure; and
- indicators of the effectiveness of the safety programme.

To achieve this the system is structured into five modules as follows:

Module 1: Notification and inventory of radiation sources and installations

- Total number of radiation sources at a given installation, classified by practices and type of sources.
- Installations of a given practice.
- Installations that possess a specific model of equipment.

Module 2: Authorization

- Administrative information about a given installation (e.g. name, address, phone number).
- History of authorizations.
- Authorization status (for example, authorization pending answer of request for safety related information in an application).
- Deadlines for administrative actions.
- History of sources that may have been in more than one installation.

Model 3: Inspection and enforcement

- Categorization of practice according to risk.
- Frequency of inspections according to category.
- Schedule of inspections in a given period of time.
- History of inspection of a given installation.
- Enforcement actions (e.g. letters of violations, penalty proposal).
- Deadlines for requirement of an action.

Module 4: Occupational dosimetry

- Persons of a given installation that required personal dose control.
- Persons exceeding an investigation level or a dose constraint.
- Persons with doses exceeding limits.
- Average doses for a given practice.
- Classification by individuals, by age, sex and practice of doses received.
-

Module 5: Performance indicators

5.1. Indicators of performance of the Regulatory Authority:

- Average time to process application for an authorization (by type of practice).
- Number of authorizations pending.
- Turn over of personnel and training of personnel.
- Inspections per year and per inspector.
- Installations scheduled for inspection, but not inspected in a given period.

5.2. Indicators of performance of individual user installations:

- Average doses (by practice) within the installation.
- Doses exceeding constraints, investigation levels or limits (by practice).
- History of non-compliance, violations and sanctions.
- List of incidents or accidents by category.

5.3. Global indicators of performance of the national radiation protection infrastructure:

- Number of doses exceeding investigation levels or limits, per practice.
- Number of accidents (by category and practice).
- Number of enforcement actions and penalties.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment Plans for Authorization and Inspection of Radiation Sources, IAEA-TECDOC-1113, Vienna (1999).

[2] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, NUCLEAR ENERGY AGENCY OF THE OECD, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Implementation of a National Regulatory Infrastructure Governing Protection Against Ionizing Radiation and the Safety of Radiation Sources, IAEA-TECDOC-1067, Vienna (1999).

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Consultants Meetings
Washington DC, USA: August 1997
Vienna, Austria: January 1998
Vienna, Austria: February 2000

Technical Committee Meeting
Vienna, Austria: March 1999

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