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FOREWORD

The application of formal quality assurance requirements by the organizations acting as nuclear safety regulators shows large variations depending on the particular Member State. In some Member States the implementation of typical quality assurance requirements has gradually become an established practice. They understand that, in order to properly discharge their responsibilities and efficiently perform their regulatory activities, planned and systematic measures, such as those established under a quality assurance programme (in some places also called quality management) have to be in place. In other Member States the establishment of such a programme by the regulator would not be considered or would even be rejected.

However, progressive regulators are giving more and more attention to the formal institutionalisation of quality assurance/quality management practices for their regulatory functions. This is necessary owing to, for example, the variety and the complexity of the activities performed by the nuclear regulator in the various licensing areas. Regulatory staff have to be trained in various disciplines both as generalists and specialists; they have to be able to make timely decisions under difficult circumstances; and they have to treat licensees equitably and with consistency. At the same time, they must be able to defend their decisions when subjected to public scrutiny.

The impact of current trends toward the privatisation of nuclear utilities and the deregulation of energy markets herald significant changes in nuclear operations. The focus on safety is the constant that has to be carried over into the competitive electricity business. In changing times, regulators have to anticipate future direction and sensitivities, and be ready to be able to meet new regulatory challenges when the need arises. Such changes could have a profound effect on, for example, work planning, resources, training, regulations, regulatory policies and priorities.

The reputation that regulatory organizations must maintain to retain public trust requires them to perform to the highest standards. Organisations performing under "crisis management" pressure typically fail to recognise the benefits of quality assurance programmes in preventing such pressures. Nowadays, it is universally recognised that no organisation can continue to improve and cope in a dynamic working environment unless a quality assurance programme is in place.

The IAEA directed extensive efforts during the years 1991 to 1995 to the integral revision of all NUSS quality assurance publications, which were approved and issued as Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (1996). When these quality assurance publications were developed, their prime focus was on requirements against which work performed by the licensees could be measured and assessed by the regulatory bodies. In this way, they only helped to facilitate the functions of regulators. No requirements or recommendations were provided on how the regulators should ensure the effective implementation of their own activities.

The present publication is a first attempt to collect, integrate and offer available experience to directly support performance of regulatory activities. It presents a comprehensive compilation on the application of quality assurance principles and methods by regulatory bodies to their activities. The aim is consistent good performance of regulatory activities through a systematic approach.

The subject of quality performance of regulatory activities seems to be a sensitive one with some regulators. It is hoped that the guidance contained in this publication will help reduce this sensitivity, and that experience and feedback from the concepts and examples will lead to its further improvement.

In thanking the many contributors to this publication, the Secretariat wishes to acknowledge the valuable time and material provided, the co-operative attitude and the willingness to discuss different approaches. Thanks are also conveyed to those who provided critical appraisals of the early drafts that helped to identify weaknesses and finalise the publication. The IAEA is especially grateful to J.Mullan of Canada and J. Stuller of Czech Republic for their contribution. The scientific secretary responsible for this work was N. Pieroni of the Division of Nuclear Power.

EDITORIAL NOTE

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1. INTRODUCTION

BACKGROUND

101. The application of quality assurance to the conduct of regulatory activities has been an IAEA agenda item since an Advisory Group meeting (AGM) held in Vienna in March 1990. The general feeling then was that the approach that was discussed could be valuable, but that its application in some countries could be difficult.

102. Between 1991 and 1995 all of the IAEA's quality assurance NUSS publications were revised and reissued as an integral set in September 1996. While these publications were developed with regulators in mind, and in such a way as to facilitate their regulatory function, the main users of the publications clearly were to be nuclear facility licensees. They could follow the guidance given in the publications to enable them to demonstrate compliance with regulatory requirements.

103. Since explicit reference to the work done by the regulator was avoided in order to focus on the full responsibility of licensees, no recommendations were provided on how regulators should manage their licensing activities to ensure compliance with regulatory requirements. Now, this publication is intended to cover recommendations that apply only to the regulatory body.

OBJECTIVE

104. The objective of this publication is to give information and good practices in the development and application of quality assurance to regulatory activities for effectively and efficiently fulfilling the requirements of its mandate. It identifies the functions that support and control activities that are essential for the regulator to successfully perform its main functions.

SCOPE

105. This publication presumes that the regulatory body and the corresponding legislative aspects have already been established and are in place. It covers the main considerations that should be addressed by the regulatory body in order to conduct its affairs according to quality assurance principles and practices, and fulfil its legislative mandate.

STRUCTURE

106. The publication is arranged in four sections. Section 2, Systematic Approach to Regulatory Processes, identifies the regulatory body's core operational areas. The quality assurance principles are applied to the activities that correspond to them. This leads to a programme comprising three functional categories that are consistent with the approach advocated in Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations. The programme is described in the next three sections. Section 3, Management, deals with those aspects of the programme that require the involvement of management. Section 4, Performance, discusses the activities carried out by the line organisation; and Section 5, Assessment, describes how to evaluate the programme.

2. SYSTEMATIC APPROACH TO REGULATORY PROCESSES

GENERAL

201. The regulatory body's mission is to ensure that the safety of the public and of the operating staff of nuclear facilities are protected. In some Member States, the regulatory body's mission also includes protection of the environment. Therefore the scope of regulatory work can cover life-cycle activities from the manufacture and use of small sources of ionising radiation, to the operation and decommissioning of complex nuclear installations.

202. The regulatory body should clearly define the organisation's main functions and should emphasise their central importance relative to the regulatory body's statutory responsibilities. When the regulatory body is represented by more than one authority, each authority should define the main function(s) for which it has statutory obligation, and the activities and responsibilities that correspond to them.

203. The regulatory authorities should concentrate on their individual responsibilities. They should ensure that the processes they use to communicate information and decisions to each other and to licensees, are efficient and that there are no gaps or overlaps.

MAIN FUNCTIONS

204. The main functions of the regulatory body are typically identified as follows:

— Regulations and guides
— Review and assessment
— Licensing
— Inspection
— Corrective actions
— Enforcement.

205. These main functions constitute the core work of the regulatory body. To do this work competently, the regulatory body should implement processes that are structured and systematic. The focus should be on nuclear safety and the accomplishment of statutory responsibilities. The level of effort should be graded to the importance to nuclear safety.

PRINCIPLES

206. To accomplish this, the regulatory body should:

— identify the management processes that support and control the work specific to the main functions; and
— define and develop these processes integrating the following quality assurance principles (P1–P15):
  — P1 Organise for success through group interdependence
  — P2 Define policies and objectives — ensure they are understood and accepted
  — P3 Define roles and responsibilities — ensure they are understood and accepted
  — P4 Initiate and expand employee involvement through empowerment
  — P5 Promote accountability concepts

— P6 Ensure competency through training
— P7 Stress leadership in managers
— P8 Plan and control work
— P9 Mutually agree on expectations
— P10 Focus on meeting expectations by establishing standards of service
— P11 Seek and use relevant experience
— P12 Make decisions based on effective communication
— P13 Measure and review performance
— P14 Strive to improve
— P15 Ensure essential records are produced and maintained.

PROCESSES

207. The attendant role of support functions and control functions that underpin the main functions should be defined and understood. The accomplishment of these functions should centre on the objectives of the main functions and on meeting the main regulatory objective of protecting safety. Annex 1 identifies these functions.

208. The complete programme of management processes should be derived by integrating the support functions and control functions with the main functions. Annex 1 shows how to derive these processes and explains how the principles (P1–P15) can apply to all functions. It also shows where the regulatory body can incorporate them into the management processes and address them in the publications that communicate the management processes to regulatory staff.

209. These management processes are defined in the regulator's management procedures. Annex 2 shows an example of the steps taken to produce these procedures.

210. When these principles are integrated into the routine internal management of the regulatory body's activities, managers can use them to guide their own performance and assess how they carry out their responsibilities. Managers should also use them to ensure that the management processes and methods they develop and use are results oriented, and that they focus on overall improvement.

211. Recognising the importance of how people interact with each other, the regulatory body should develop and promote a set of human values, or ethics, to guide the every-day treatment of staff and the operation of the organisation. An example of a set currently in use is given in Annex 3.

3. MANAGEMENT

GENERAL

301. This section covers the activities that are accomplished by management. These activities are primarily strategic in nature. They establish direction, and how the regulatory body will organise and manage its affairs.

302. When the support functions referred to in para. 207 and Annex 1 are distributed into the three general categories of management, performance and assessment, the responsibilities of

the senior managers and the line organisation concerning the management system become clear. At the same time, the management system topics that need to be covered in management's policies and procedures are identified.

303. The distribution referred to in para. 302 is covered separately below and in Sections 4 and 5 respectively. The systematic approach (or quality assurance programme) means integrating the activities covered in these three sections and implementing them in accordance with processes that derive from the guidance given in them.

LEADERSHIP

304. The regulatory body should have arrangements in place to maintain and improve leadership skills. Examples of indicators of leadership skills in the current context are given in Annex 4.

305. Management policies should endorse leadership skills in senior and line managers. (In general senior managers set policies and strategies, and line managers carry them out. Refer also to 50-C/SG-Q5, Assessment of the Implementation of the Quality Assurance Programme.) Policies should promote a commitment to good leadership and should recognise that the leadership of managers is the key to the organisation's success. Basic issues enhancing senior management capability in this respect are shown in Annex 5.

306. Managers should be committed to good leadership and their performance in this area should be measured. A general measure of the effectiveness of managers should be obtained by observing the interplay between the following:

Success

— does the managed organisation meet its statutory requirements and organisational objectives?

Skills

— do managers have the right skills, abilities and attitudes for leadership?
— are they able to learn with change?

Structure

— how do managers arrive at decisions?
— are work and responsibilities organised?
— is accountability promoted?
— which questions can be asked and which cannot?

Process

— do managers foster and practice co-operation and sharing?
— do they empower their staff?
— do they reward, encourage and motivate a high level of efficiency and co-operation?

ORGANIZATIONAL FACTORS

307. In consideration of the scope of work undertaken by the regulatory body, senior management should structure the organisation so that the staff can perform competently and

efficiently. The structure should benefit the performance of individuals, work units and the overall organisation.

308. Senior management should ensure that each individual and work unit knows and understands their roles and responsibilities and how and when they need to communicate with each other. Job descriptions and lines of communication within groups and across organisational interfaces should be established and formalised.

309. This interdependence should be reflected in the organisational structure and in the corresponding roles and responsibilities, and should emphasise teamwork, co-operation and communication, with the focus on meeting expectations and service standards ("service standards" are explained in Annex 10).

310. Senior management should define and identify the functional responsibilities, reporting relationships and the levels of authority of senior managers, committees, line managers, supervisors, organisational units and staff. Senior management should clearly define the scope of accountability of all staff, and where in the organisation regulatory decisions are to be made.

311. In general, the responsibilities of individuals and units of the regulatory body should be such that senior managers establish the organisation's strategy, line managers establish the corresponding tactics, and supervisors conduct the routine operations.

312. Senior management should assign responsibilities so as to empower people by giving them increased organisation and support with a corresponding reduction in supervision. To empower people, managers should push authority and decision-making down to the lowest effectual level in the organisation where the appropriate skills exist, and encourage employees to seek more efficient ways of doing their work.

313. Accountability and empowerment should complement each other. When management empowers employees, management should also hold them accountable. Each organisational unit, manager and employee should understand that they are responsible and accountable for the work they perform and the decisions they make.

POLICIES

314. Senior management should ensure that each unit and employee understand how the work they are doing relates to the organisation's mission, policies, and objectives. Therefore, senior management should define how the organisation will conduct its operations, and should communicate its expectations to regulatory staff through published internal policies and procedures. Annex 6 is an example of an internal policy.

315. Senior management should also ensure that external policies that apply to licence applicants and licensees are also identified and produced.

316. Policies should reflect senior management's attitude towards excellence of performance, and how it should be achieved during routine operations. Senior managers should take highly visible actions to seek out and reward excellence and to seek the input of individual workers regarding improvement. These actions are necessary to give credence to written proclamations.

317. Senior management is responsible for:

— defining what policies are required
— identifying the subject areas that should be addressed
— producing the policies and making them available when they are needed
— ensuring that individuals and organisations who will be affected by them are consulted
— ensuring that the production, issue and revision of policies are controlled.

Sections 2, 3, 4 and 5 of this publication serve as a guide to the subject areas that policies should cover. Some examples of policy subjects are covered in Annex 7.

318. These policies should establish inter alia, the basis for determining and defining the extent and depth of all regulatory work, the limits to discretion, the method of producing regulatory requirements and guidance, the standards and the methods for assessing and approving licence applications, for assessing licensee competence, for performing compliance inspections and for enforcing licensing requirements.

319. Policies should specify how regulatory work should be prioritised and performed. These policies should also establish and cultivate principles that promote proportionality, transparency and practicality, and the broad sharing of information and ideas in the conduct of the day-to-day work. They should provide the individuals performing the work with the necessary information, tools, support, and encouragement to perform their tasks properly. Additional information on policy documents is contained in 50-C/SG-Q1, Establishing and Implementing a Quality Assurance Programme, Section 3.

STRATEGIC PLANNING

320. Strategic planning should enable the regulatory body to be well positioned to anticipate future needs early. The strategic plan should define the direction and the actions that the organisation will take to fulfil its mission, and should align the organisation with the future. It should steer overall policy, goals and direction for future activities and should establish the general priorities.

321. Senior managers should begin the process by placing a high emphasis on setting mission objectives and on monitoring the organisation's performance against them. They should formulate a mission statement that is based on the legislated mandate, and describe what the organisation does, how it does it, and for whom.

322. Senior managers should be continuously looking ahead to visualise what the organisation should be striving to be in the future. They should also be monitoring the external environment and be able to anticipate changes.

323. These may include changes to regulatory emphasis, regulatory methods, roles, how the top management team functions, and may even require changes to personnel. Adjustments to concepts and operating methods should be made accordingly.

324. Senior managers should systematically produce plans and strategies for the short term and for the longer term, and should review and update them periodically. Line managers

should break the strategic plan down and produce individual plans for their own units that align with the strategic plan.

325. Examples of typical subjects that could be addressed in strategic planning are shown in Annex 8. Some considerations for developing an effective strategic plan are given in Annex 9.

326. Strategic planning should be a disciplined effort by senior managers that produces fundamental decisions and actions for shaping the nature and direction of all of the regulatory body's activities. Strategic planning should influence senior managers to:

— think strategically;
— clarify the future direction;
— make decisions today in anticipation of future consequences;
— develop a coherent and defensible basis for decision making;
— assess organisational effectiveness;
— improve performance; and
— build teamwork and expertise.

327. Once the organisational objectives have been adopted, senior managers should provide the authority and resources necessary for the line managers to achieve them.

328. Senior managers should ensure that the subsequent operational activities that units budget for and plan to do, are aligned with the strategic plan. Senior managers should allocate the resources that these units require.

329. Senior managers should ensure that individual line managers meet regularly with their staff to keep them up-to-date with changing organisational goals, general organisational direction, concerns, changing priorities, developing problems, resource allocation, training needs, scheduling and interfacing problems.

PROCEDURES

330. Management procedures document the processes to be used to implement policies. They should:

(1) Detail the functions, authority, responsibilities and accountabilities of the unit and the individuals in the unit. For the individuals these should take the form of job descriptions.

(2) Define the responsibilities and the internal and external lines of communication that apply to the activities the unit carries out.

(3) Specify what activities are to be carried out by the unit and who is responsible and accountable. Where additional detailed working guidance is needed, the document should be referenced.

(4) Specify how work is received, assigned, planned, controlled and completed.

331. Line managers should develop processes for managing work assignments and resources, and for achieving objectives and document them.

332. When the procedures are implemented, these processes should provide individuals with the decision-making authority and accountability they need to do the work.

333. The procedures that describe these processes should also cover the development of interface arrangements, and instructions for performing the work. Key activities, outputs, records, and the associated responsibilities should be identified.

334. Specific details of how work should be assigned and managed either by individuals, by a unit team or by a multi-disciplinary team should also be covered.

335. The type and format of working procedures can vary according to application. They should specify expectations and criteria for doing work satisfactorily. Management procedures and working instructions should be updated on a regular basis and when needed. Additional information is contained in 50-C/SG-Q1, Establishing and Implementing a Quality Assurance Programme, Section 3.

DOCUMENT CONTROL

336. Management should establish a system to control the preparation, review, approval, issuance and revision of documents that relate to the accomplishment of the main functions.

337. The document control system should ensure that regulatory staff are provided with up-to-date regulatory requirements and policies, and are issued with the appropriate revisions of documents for performing their work. External documents that are the product of their work e.g. regulatory standards and guides or reports should also be controlled and available. Additional source information on the control of documents may be obtained from the relevant sections of 50-C/SG-Q3, Document Control and Records.

RECORDS

338. The regulatory body should identify documents, records and information as an asset that should be protected for its intellectual content. (In this publication, these documents, records and information will be referred to as information holdings.) Management should establish a records system and ensure activities associated with managing information holdings are co-ordinated and effective.

339. The system should ensure that relevant information is collected, processed and retained. Information holdings should be readily retrievable to support decision making, meet operational requirements and protect legal, financial and other matters in the interest of the public, the regulator and the licensee/applicant.

340. Management should identify the information holdings that should be retained from internal and external sources. Information holdings should show that regulatory objectives and responsibilities are being satisfied. They may be in the form of e.g. regulatory documents, licence documentation, procedures and instructions, licences, letters, memoranda, e-mail, facsimiles, reports, calculations, minutes of meetings, interviews, news letters, news bulletins, published material, enforcement orders, inspectors' certificates, drawings, photographs and electronic media.

341. Information holdings should be classified as to their type, and requirements should be established for developing, managing and retaining each class. The most common and useful characteristics for classification are according to their use, purpose, users, origin and term. For example, based on their purpose, information holdings can be grouped as shown below to:

(1) Direct actions as in a regulation;

(2) Authorise actions as in a licence, or permit;

(3) Recommend or explain actions as in a guide;

(4) Inform as in an information document, publication, or news release;

(5) Transactions as in letters, memos, or completed forms;

(6) Record actions and decisions as in reports, minutes, photographs, videotapes, sound recordings;

(7) Characterise or describe items or places as in plans, maps, drawings, photographs.

342. Information holdings should be produced, collected and filed as specified. They should be classified as they are received, or as they are produced, and captured and stored according to procedures. Information holdings should be given a unique identifier, catalogued and maintained for convenient retrieval.

343. The sensitivity of the information and data should be considered. Information holdings should be protected regardless of the form of medium. Availability, and retention and disposal schedules and rules should be specified and observed. These include rules for e.g. preservation, confidentiality, security, version control, distribution, routing and notification, viewing, search and retrieval, information association, reusability, history of usage, archival, and destruction.

344. Information holdings should be organised to permit reconstruction of the evolution of policy, and operational and licensing decisions. Information of archival importance should also be classified, organised and compiled so that it is readily available for the examination of decision making.

345. To ensure the long-term availability of information holdings, management should ensure that users observe the rules regarding e.g. preservation, confidentiality, security, version control, distribution, routing and notification, viewing, search and retrieval, information association, reusability, history of usage, archival, disposal and destruction. Additional source information on records may be obtained from the relevant sections of 50-C/SG-Q3, Document Control and Records.

SERVICE STANDARDS AND MONITORING

346. Senior management of the regulatory body should ensure that internal standards of service are developed and implemented for each regulatory activity. Annex 10 explains service standards. The implementation of internal service standards should enable one organisational unit within the regulatory body to anticipate reliably the minimum level of service it may expect when it approaches another unit within the organisation with a work request.

347. Line managers should manage their work units based on performance and on the level of service provided. They should ensure that adequate resources are allocated to meet commitments, and that their staff are properly trained. Individual staff members should be responsible and accountable for working within the framework established by the service standards. Delivery targets for the service should be stated. They may be qualitative or quantitative. Some examples of delivery targets are given in Annex 11.

348. Line managers should establish service standards for the work done by their individual units. These standards should take into account primarily the needs of the internal organisational units, the needs of other public authorities and the needs of the public. These parties are usually referred to as "clients". Where safety is a concern, the expectations of licensees and applicants should also be considered.

349. Line managers should consult with their staff when they are developing service standards. The standards they set should be meaningful to those who benefit from them. They should ensure that the service they describe in the unit's procedure, matches the unit's roles and responsibilities.

350. Line managers should inform clients of the service they provide. They should ask clients to define their needs, so that the results and information they require may be provided on time. Clients should also be made aware of their responsibilities and how they too can affect the satisfactory delivery of the service.

351. Line managers should monitor the performance of their unit. They should keep themselves aware of operational factors and the expectations of clients and make any necessary adjustments and improvements. They should establish a means for client groups to report on their satisfaction or dissatisfaction, and to suggest improvements. Line managers should review and use this feedback information to introduce improvements.

352. Line managers should also monitor and assess influences that are internal and external to their unit. Internal influences include employees, policies and workload. External influences include clients, other regulatory unit partners, outside organisations, licensees and technology.

353. Line managers should review their unit's performance. As a minimum, the review should determine whether the level of service and the quality of the unit's work are adequate. If results show that performance is inadequate, action should be taken to improve it. (See paras 415–420.)

354. Line managers should also periodically assess their own performance and how it contributes to meeting their unit's objectives. (Refer to Section 5, Management Self-Assessment.) These reviews should involve consultations with supervisors, staff and client groups.

355. Line managers should make the results of these reviews available to staff, senior managers and clients. Management problems that hinder the achievement of objectives should be identified and corrected.

356. Service standards should cover the following topics:

(1) Mission statement of the unit.

(2) Description of the service.

(3) Method of requesting the service.

(4) Reciprocal responsibilities of clients.

(5) Unit procedure(s) reference.

(6) Deliverables.

(7) Delivery targets.

(8) Monitoring of performance.

(9) Feedback from clients.

(10) Annual review and report to management.

FINANCIAL AND HUMAN RESOURCE PLANNING

357. The regulatory body as a government organization should plan and arrange for the funding necessary to ensure it can meet its regulatory obligations. An appropriate and efficient financial control system should be implemented. It should be capable of signalling when optimisation is not being achieved.

358. Senior management should decide on the degree of centralisation that should be applied. For example, the budgets for communications, and for supplies might be centralised and administered by the appropriate central manager, while the budgets for duty travel, temporary help, or consultants might be administered by the various line managers or supervisors.

359. Managers should review budgets regularly and make adjustments to their work plans based on safety priorities. They should measure and report on their overall performance in accordance with established monitoring and control procedures. An example of the phases of a typical financial planning cycle are described in Annex 12.

360. Since the effectiveness of the regulatory body also depends on its human resource base, long term human resource and succession planning are essential to meeting immediate and long term objectives. This planning should help identify emerging issues, regulatory priorities and the corresponding changes in resource requirements.

361. Succession planning should ensure that:

(1) Vulnerable positions are identified and monitored.

(2) Critical positions are occupied by competent people at all times.

(3) No significant information, experience, or expertise is lost due to the unavailability of the employee.

(4) Changing operations areas and priorities are taken into account.

(5) Succession planning and career planning are linked.

362. The human resource plan should result in predicting the size and composition of the staff that the regulatory body will require based on the scope of responsibility.

363. The regulatory body should have full time staff capable of judging the safety of the facilities it regulates. When the services of consultants are used, the regulatory body should have staff who can assess the adequacy of their work.

364. Human resource planning should take into account the qualifications and training needed to ensure that the proper mix of technical expertise, engineering judgement, and management, health and safety skills are available. Additional information is given in 50-SG-G1, Qualifications and Training of Staff of the Regulatory Body for Nuclear Power Plants.

HUMAN RESOURCE DEVELOPMENT

365. To ensure that staff with the proper training and experience are available at the right time, the regulatory body's strategic plan identifies broad objectives and target areas for human resource development considerations. Management should then implement policies that stimulate professional, technical, managerial, communication and interpersonal skills that will ensure these objectives can, and will be met. Annex 13 gives some suggestions for creating opportunities for developing human resources.

366. To ensure that people will be adequately trained for the work when it is assigned, the management policies should establish clear lines of management's accountability for planning and delivering human resource development programs. These programs should ensure that the progress of all staff is determined according to their demonstrated skills, abilities, and experience rather than on perceptions based on years of experience, or level or type of education.

367. Management should ensure that opportunities for career progression are available to senior specialists to prevent them from becoming locked into their specialist positions. Personnel selected for management positions should have demonstrated their management and leadership skills, e.g. in trial positions, in developmental positions, or through mentorship, prior to being selected for the position.

368. Managers should promote and encourage the career development of junior staff in a timely manner. In this regard, senior management should ensure that the line managers make staff with unique skills and experience available to the wider organisation.

TRAINING

369. The regulatory body should implement a systematic approach to training and ensure that senior managers, line managers and staff are well-trained and competent to perform their jobs and duties as described in internal documents, and that through continuing training they maintain their competence. Training programmes should be structured to ensure that they addresses the specific needs of individuals as well as those of the overall organisation. Annex 14 is an example of the factors to consider for establishing effective training programmes.

370. Corporate, divisional and personal training programs should be developed. These programs should be subject to ongoing review and should be upgraded when needed improvements or other enhancements are necessary. Annexes 15 and 16 are examples of strategic and operational training programmes.

371. Senior managers, and line managers should have the training necessary to carry out their managerial responsibilities. Annexes 4 and 5 provide information on some of the skills that managers should have, and Annex 17 refers to some of the training aspects.

372. Senior managers, and line managers should be closely involved in the training that their staff need for the organisation to fulfil its mandate. They should devote thought, time and the resources necessary to define the existing and upcoming areas where training is needed.

373. Given the safety consequences of incorrect decisions, managers should continuously review the training of staff and, where applicable, of consultants. Needs assessments and job analyses should be performed to ensure staff availability.

374. When the application of multiple skills is useful, managers should promote teamwork. The staff should be trained to work effectively in teams.

375. Records should be kept for the training that individuals have received and the experience they have gained.

INTERNAL COMMUNICATIONS

376. The regulatory body should adopt a communications strategy that promotes the unreserved sharing of information and instructs, guides and motivates people to work efficiently. The management of the regulatory body should lead by example by communicating its policies, programmes, objectives, strategy and operational decisions to the staff.

377. The regulatory body should ensure that licensing decisions and decisions that affect the operation of the regulatory organisation are made based on accurate, up-to-date information that has been reviewed and approved. Such decisions should not be taken without prior consultation and discussion with those affected by them.

378. Managers should ensure that the information employees need for making decisions is transparent and available to them when they need it. This includes for example, corporate policies, unit authority, responsibility and accountability, regulatory requirements, objectives, priorities, service standards, and work procedures and instructions. The communication methods and skills of managers should be measured to determine if leadership requirements are being satisfied. (See para. 306).

379. Effective communication between managers and staff is essential to performance and personal self-worth. Managers and staff should be held accountable for keeping vertical and horizontal communication channels open. The preferred methods of communication should be identified and followed.

380. Management should define expectations, rules and limits associated with:

(1) Formal meetings, informal meetings, licensing meetings, planning meetings, analytical meetings and meetings for information, etc. and how they should be managed.

(2) Meeting attendance, frequency, agenda and minutes; circulation of minutes.

(3) Communication up and down organisational lines.

(4) Communication and consultation with remote locations.

(5) Timely consultation and communication across organisation interfaces.

(6) Multi-disciplinary team assessments and decisions.

(7) Recording and confirming decisions.

(8) Resolving and recording differences of opinion.

(9) Verbal, written and electronic communication and consultation.

(10) Protecting sensitive information and data.

EXTERNAL COMMUNICATIONS

381. Management of the regulatory body should state its policy with regard to enlightening and informing the public and external organisations on the health and safety aspects of its regulatory activities. The major organisations with whom the regulatory organisation is to communicate should be identified. Procedures should indicate what information should and can be discussed, what information can be transmitted, and who is responsible for communicating official regulatory policies, positions and decisions.

382. Management should prepare objectives for managing external communications. The objectives should address, for example, monitoring of the communications environment, the preparation of communications plans, the provision of communications training and advice to regulatory staff, the provision of editorial comment on communications with government offices and the media.

383. Policies, guidelines and procedures should cover, for example:

(1) Communication with the public and the media, and consultation with the public.

(2) Official interfacing with applicants and licensees.

(3) Communication with government authorities and international organisations.

(4) Regulatory board meetings, public meetings, hearings, and enquiries.

(5) Communications planning and co-ordination.

(6) Crisis communication.

(7) Access to information and privacy.

(8) Electronic communication, advertising and communications training.

INTERFACES WITH LICENSEES/APPLICANTS

384. Management of the regulatory body should establish rules for ensuring that both the regulatory body and licensees/applicants have confidence in the information they receive from one another regarding licensing requirements and compliance.

385. Management should specify requirements for communicating with licensee/applicants and for maintaining an arm's length relationship (independence) with them while obtaining the factual information needed to resolve issues, minimise conflicts, and prevent misunderstandings.

386. Communication with licensees should be conducted in a competent manner, should be based on a clearly defined interface, and should be guided by principles of professional behaviour.

387. Management should establish interface arrangements that are effective and satisfy the safety needs of both parties. Management should address all levels of interaction, formal or informal, and oral or written. The arrangements should be implemented by each staff member of either organisation who participates in meetings, discussions, or in other interactions between the two organisations.

388. Management should ensure that meetings between organisations are conducted efficiently and are in the best interest of safety and the public. Management should establish requirements for ensuring that meetings are planned, the right people attend, and participants are prepared and available to attend. Agreed interface norms for presiding over meetings and for conducting meetings between organisations should be established. See Annex 18 for an example of interface norms.

389. An agreed communications model for the signing of a written communication should be established and followed. The communications model should provide the steps that should be taken to ensure that all expectations are understood before any work is started. See Annex 19 for an example of an agreed communications model.

390. Management should establish a communications protocol and define the rules that should be applied for the various levels of official and unofficial communication with licensees/applicants. See Annex 20 for an example of an agreed communications protocol.

391. Management should establish a means of ensuring there is a mutual understanding between the regulatory body and licensee/applicants of issues that are urgent. It may be useful to prioritise safety issues. See Annex 21 for an example of an agreed method.

EXPERIENCE FEEDBACK

392. Management should actively promote feedback on the lessons learned from past experience. Senior managers, line managers and organisational units should document their experience so that others may benefit from the experience.

393. Managers at all levels should promote an organisational culture that is committed to excellence by recognising successes and avoiding past failures. Protocols should be established to allow ready access to previous experience, decisions, the basis for the decisions made, reports and minutes of meetings.

394. Senior managers should establish a means of ensuring that other information, such as new technology and lessons learned from external organisations that could affect operations, is also screened, evaluated and filed for later consideration.

4. PERFORMANCE

GENERAL

401. This section covers the activities that are accomplished by the line organisation. These activities are primarily tactical in nature. They relate to the performance of the main functions and how they are controlled at the working level where good performance or quality is obtained.

WORK PLANNING AND CONTROL

402. Regulatory work should be planned and controlled to ensure that the organisation's objectives are met systematically and on time. This requires establishing work priorities and appropriate lines of communication and preparing criteria that are based on the correct revision of regulatory policies and requirements.

403. The work that has to be done should be identified. Work plans should be prepared by the line organisation based on:

(1) High level plans derived from the strategic plan and routine/recurring regulatory activities such as preparation of regulatory requirements, reviews, assessments, inspections and

(2) Anticipated work such as reviews and inspections of submissions for licensing and re-licensing, activities associated with enforcement actions, revision of regulatory documents.

Annexes 22–24 are examples of various types of plans.

404. The work should be described in preliminary work descriptions. The detail should enable decisions to be made on their priority. This information should be provided to prepare annual budgets, to plan multi-disciplinary projects and non-routine work requests.

405. The scope and anticipated level of effort should be defined. The regulatory policies and requirements that apply should be referenced, and the proposed work should be reviewed by management to confirm that it accords with the regulatory mission, strategic plan and operational plans. Management approval of the preliminary description should be required to justify the work and authorise the refinement of the scope and a more accurate definition of the level of effort.

406. Significant work activities should be defined and planned (see para 408 below). To manage the work during its entire cycle, the work should be broken down into well defined components. The individuals or internal unit responsible for each component should be identified. The most qualified staff regardless of unit affiliation should be brought together to perform the work.

407. Commitments made in organisational unit service standards should be observed. Each unit should measure its performance against these standards. Performance measures should ensure everything that is important is measured, and only those things.

408. To define and plan the work that is significant, the following should be done:

(1) Identify key interfaces

(2) Prepare a scope.

(3) Prepare objectives.

(4) Identify the various tasks involved.

(5) Identify who is responsible for these tasks.

(6) Prepare a work schedule; identify the resources needed.

(7) Specify the regulatory requirements associated with the work.

(8) Specify the service standard.

(9) Specify the work controls.

(10) Identify the expected deliverable.

409. The detailed project plans and budget commitments should be reviewed and approved by management to confirm that management expectations can be met. Work should be supported by a formal authorisation. The financial management system should be integrated with the work management system to monitor performance and supply data on the final level of effort.

410. At the time of assigning work, line managers should review existing work-loads and schedules to confirm that new assignments can be integrated. Line managers should be responsible for ensuring that personnel have received the necessary training, resources and directions.

411. Work should be performed in accordance with the instructions and criteria specified in work plans or work requests. Consistency, currency, and fairness of application of instructions are essential to their worth. Changes in scope should be approved before being undertaken by the individual or organisational unit. The detail in work plans and instructions should be commensurate with the complexity and importance of the work. Additional information on working level instructions is contained in 50-C/SG-Q1, Establishing and Implementing a Quality Assurance Programme, Section 3.

412. Work should be subjected to independent checks and reviews to ensure that it meets the requirements that have been established.

413. The progress of work should be monitored and reported. The status of the work should be measured at the level where the work is performed. Regulatory decisions should be justified, documented and recorded.

414. Performance should be assessed by measuring results against the specified job requirements, the time spent, the status of the work, and comparing these with the original plan. Performance results should be reported and should be used for improving future performance, planning and estimating, and guiding strategic planning and subsequent regulatory decisions.

NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

415. Errors, deficiencies and omissions in regulatory activities that resulted in, or could have resulted in the regulatory body's failure to meet statutory requirements should be identified and corrected. The safety impact should be assessed and reported to management.

416. When a statutory requirement is not met or when the safety impact is significant or could be significant, the root cause of the non-conformance should be determined and corrected to prevent recurrence. Additional information is given in 50-C/SG-Q2, Non-conformance Control and Corrective Actions.

IMPROVEMENT

417. Line managers should know the existing status of their work unit's processes to quantitatively evaluate the effect of the improvements they may wish to introduce. Line managers should assess the quality of the services their units provide, and how effective their operational processes are in preventing non-conformance in their work. They should allocate the resources to where they are needed to solve a performance problem.

418. Line managers should identify and track results in their own work units, including non-conformance and failures to meet service agreements and costs. They should encourage their staff to consistently seek new, more innovative ways to improve performance, efficiency, and effectiveness.

419. Line managers should implement a process to promote continuous improvement and foster the belief in every employee that he/she makes the difference in the organisation's overall performance. They should review and affirm the existing methods used to manage the work done by their units, and should eliminate unnecessary steps.

420. Line managers should focus simultaneously on improving management processes and adapting to changing strategic needs. They should develop less complicated alternative processes to maximise performance using the existing resources.

REGULATIONS AND GUIDES

421. The development of regulations and guides should be systematic to ensure coverage of all major aspects to be dealt with during all stages of licensing. Current international practices in the relevant areas may be taken into account. The content material in regulations and guides should be consistent from one document to the other.

422. Regulations should provide advance information on the legal safety requirements for each stage of issuing a licence or permit. They should express the minimum requirements that the regulatory body considers necessary for achieving and maintaining safety.

423. The regulations should be used as a basis and reference to identify the standards and guidance material may be required. Their field of application should be clear. The extent to which they apply to different stages in the process of issuing licences or permits, or to special aspects, e.g. back-fitting, temporary shut-down, should be evident.

424. Regulatory standards and guidance material should be readily available to all concerned. They should supply users with the right amount of technical detail that can be supported by legal opinion.

425. The development of individual regulations and supporting guidance documents should be according to a work-plan and schedule. Planning should include consideration of the need for adequate financial and human resources.

426. The development process should also indicate what steps should be taken to produce the documents. These steps should cover confirming that the document is needed and making a proposal, how each class of document should be produced, and the requirements for content, format and revision. Annex 25 shows an example of a process for producing regulatory documents.

427. The types of regulatory guidance documents that may be required should be identified and their intent and legal status should be defined. See Annex 26 for a typical breakdown of regulatory documents and their definitions. A needs-identification technique should be used to identify the full suite of the documents that will be required. For example, Annex 27 shows a method of establishing category groupings in each of the main life-cycle stages.

428. The adequacy and applicability of regulatory documents based on experience feedback information should be assessed. Revisions and improvements should be made when necessary.

429. A directory of regulatory documents may be created and kept current. Regulatory staff should be trained on the use and interpretation of regulatory documents. Additional information is contained in 50-SG-G9, Regulations and Guides for Nuclear Power Plants.

RESEARCH AND DEVELOPMENT

430. The research programme should be operated in order to obtain knowledge, expertise and advice for the variety of scientific, technical and organisational disciplines involved in regulatory activities, providing them with support and supplementary resources.

431. The scope of the regulatory research and development programme should be specified and established. The programme should serve the needs of the operational divisions in carrying out their mandate. Arrangements should be defined and implemented to ensure that the demands of operational divisions are identified, reviewed, and addressed in an orderly way.

432. Planning for research and development should take into account short-term needs and longer term strategic considerations. Prioritisation should be based on the importance of research projects to regulatory licensing decisions, and to the regulatory body's obligations to the public.

433. The operational divisions should be responsible for proposing short-term projects and for justifying them. The operational divisions should define the technical requirements of the project, the intended use of the results, and the final acceptance of results. The research division should be responsible for the longer term projects.

434. The performance of research and development contract work should be monitored with respect to financial commitments and technical progress.

435. The project planning process should incorporate the arrangements discussed below:

(1) *Proposal Stage*
Projects should be proposed and ranked in priority.
Proposals should be submitted for review and approval.

(2) *Review*
The merits of each proposal should be assessed based on
(i) the availability of funds;
(ii) corporate policy and priorities; and
(iii) public and licensing priorities and considerations.
The proposal should be revised and approved.
The funding should be allocated.

(3) *Project Implementation*
A work statement should be initiated.
Criteria for the evaluation of contractors should be prepared.
Proposals should be solicited.
Proposals should be reviewed and a contractor should be chosen.
A contract identifying review and delivery milestones should be issued.
Meetings should be scheduled to review progress and output.
Compliance with contract and milestones should be monitored.
The receipt of deliverables should be confirmed.
The final report should be reviewed and accepted before issue.

(4) *Utilisation*
Results from the study should be distributed
The training of staff should be planned and carried out
Feedback information should be requested, reviewed and used

REVIEW AND ASSESSMENT

436. The reviews and assessments performed by the regulatory body should determine if safety requirements as identified in regulations, standards and guides have been satisfied by the licensee.

437. Reviews and assessments should be planned and the results recorded. Decisions on acceptance should be based on predefined criteria, and on precedents and judgements. This information should be clearly documented and understood. Annex 28 is an example of a review and reporting process.

438. If the review and assessment is for a licence application, it should involve preliminary planning of the work, ongoing comment and decision making, and communication of the results of reviews and assessments to the licence/applicant.

439. In those cases where the complete review and assessment process, from its beginning to a final decision, is lengthy and complex, arrangements similar to those discussed in paras 459–467 for inspection, should be instituted.

440. A single individual or unit (the leader or lead unit) should be given the responsibility for planning and directing the entire review, and for identifying the subject areas/topics that will be reviewed and assessed.

441. The leader or lead unit should ensure that the criteria to be used for the review and assessment, have been developed and are available, and that the review and assessment process together with the milestones, and the techniques to be used, have been defined and are followed.

442. The leader or lead unit should establish formal channels of communication with the licensee/applicant, and with other interested parties. Liaison and communication procedures with other governmental bodies should be established, and the subject areas that they will review should be identified. Information exchanges should be conducted or followed up in written form. The receipt and transmittal of this information should be logged.

443. Preliminary reviews should be scheduled and carried out to ensure that the information supplied is sufficiently complete and accurate for final review. Review and assessment plans should be adjusted if it becomes necessary to seek additional information.

444. The findings from reviews and assessments should be documented and communicated to licensee/applicants. When reviews and assessments have been completed, the licensee/applicant should be notified officially. The areas/topics that are not acceptable should be identified. The basis for related licensing decisions should be documented and justified.

445. Arrangements should be specified for recording official meetings and hearings and for issuing minutes of proceedings. Additional information on reviews and assessment is contained in 50-SG-O9, Management of Nuclear Power Plants for Safe Operation.

LICENCE ISSUE AND REISSUE

446. The regulatory body should authorise a specified activity, or set of activities, for a facility or an item, by means of official documents that are based on legislative authority. These official documents are the licences or permits. Once issued they should be binding on licensees unless and until amended. The issue and reissue of licences/permits is the chief means the regulatory body uses to exercise its regulatory control.

447. Based on the legislated requirements, the regulatory body should specify its process for issuing and renewing licences, and for reviewing and acting upon the information submitted by licensees following their issue. This process should provide for referrals to other authorities involved in licensing, and for clearly articulated conditions and schedules. Flow-chart examples of the process used to grant a facility licence, and to grant a licence to an operator are given in Annex 22 and 23 respectively.

448. The procedures that the regulatory body applies for the licensing process should ensure that the details discussed in paras 449–456 are addressed.

449. The various types of licences/permits, their format, content and specified use should be defined. The precise identification of licence/permit holder and facility and their importance should be clear.

450. The milestone location of the licence in the overall licensing process, and the legal implications for applicant and regulator should be known. The period of validity for licences/permits should be stated for each licence.

451. The regulatory body should also use its licensing process to establish directly, or by reference, the conditions governing safe performance or use. They should be clearly specified to the licensee. Licence conditions should be comprehensive, consistent, logically composed and precisely scheduled. Examples of licensing conditions should be available to regulatory body staff, identifying their scope, and how and when they should be applied.

452. The issuing process should identify who the issuing authority is, and the decisions and actions that are to be taken before a licence/permit is issued. The documents that form the basis for issuing a licence/permit should be identified, retained, and logged for easy access and retrieval.

453. Amendments to a licence/permit should be carried out according to specified requirements including consideration of the consequential effects on other documents. The experience and circumstances that led to a licence/permit amendment should be recorded.

454. Following licence/permit approval, review activities should be performed as specified. For example, the information received in accordance with the requirements of the licence/permit should be reviewed.

455. The results of such reviews should be communicated internally to other appropriate personnel, and to other government bodies and the public according to specified protocols.

456. The data should be collated systematically to establish the ongoing status of compliance with the licence. When licence/permit violations occur, action should be initiated and taken as specified. Additional information on licensing is contained in 50-SG-G8, Licences for Nuclear Power Plants: Content, Format and Legal Considerations.

INSPECTION

457. The inspection programme should be comprehensive and thorough. It should provide a high level of confidence that applicants/licensees are identifying and solving actual and potential safety problems and obeying the law.

458. Inspections should be carried out at the various facilities on items and systems, management programmes, and on the activities of applicants/licensees. These inspections should be planned to verify that applicants/licensees are complying with the approved safety objectives and other requirements specified in the licence/permit, or in regulations. Annex 24 is an example of how to produce an inspection plan.

459. The inspections should be performed according to specified instructions and should be co-ordinated by planning. The instructions should incorporate requirements that will determine if regulatory requirements are being met. They should also include requirements to determine if the practices of applicants/licensees are identifying and solving actual and potential problems that could compromise safety.

460. Preparations should be made to be able to accommodate planned inspections and reactive inspections during the term of the licence. Planning should take into account:

(1) The variability in emphasis with facility, safety consequences and licensing stage.

(2) The performance of the licensee/applicant.

(3) The kind of inspection plan needed.

(4) Whether additional training and specific inspection procedures and instructions are needed.

461. Objectives should be determined and specified to guide the conduct of planned inspections. The programme for planned inspections should link specific inspections to the applicant/licence's performance, or to the completion of activities during the term of the licence, and to their safety significance. The timing, duration and frequency should be such that they provide adequate coverage to establish that regulatory requirements are being met. Emphasis should be placed on real-time checks of ongoing activities.

462. In response to unexpected or unusual circumstances, reactive inspections should be initiated in accordance with a specified protocol. The protocol should identify e.g. responsibilities for initiating the inspection, interfacing with authorities, determining that the inspection is necessary, authorising the inspection, obtaining the resources, and planning it and carrying it out.

463. Inspection of the various facilities at their different stages of licensing should be carried out according to the requirements specified in the particular inspection plan. Measuring and test equipment should comply with 50-C/SG-Q4, Inspection and Testing for Acceptance.

464. Inspection plans should identify the following and should be sufficiently flexible to allow for unforeseen circumstances:

(1) The inspection areas, the extent and frequency of inspection.

(2) The resources (resident and non-resident inspectors, and consultants) required and their training.

(3) Schedules and the areas of particular interest.

(4) The inspection method and preparation.

(5) Special considerations.

(6) Reporting requirements.

(7) Those responsible for reviewing inspection results.

(8) Those responsible for compiling, integrating and summarising the results to determine status of compliance.

465. Inspection results should be reviewed with the licensee before leaving the inspection site.

466. A systematic process should be used to review inspection results and to integrate them with other existing information to arrive at a decision on the real-time compliance status of the facility or item. The proceedings of this review and the decision taken, together with its

justification, should be documented. The results of the inspection, review and the decision taken, and the justification should be communicated to the licensee/applicants in accordance with procedures.

467. The records of the inspections, the reviews performed, the decisions taken, and the response and actions taken by the licensee/applicant should be catalogued and collated. This information should be readily available when they are needed again for integration with later inspection results. The process of inspection, review and decision making should be continuous. The records of inspection, reviews and decisions should also be catalogued and filed as permanent records according to requirements. (See Section 3, Records). Additional information on inspection is contained in 50-SG-G4; Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants.

TECHNICAL SUPPORT

468. An internal or external technical support organisation should be utilised if necessary to support the performance of regulatory activities. The regulatory body should define the responsibilities, interfacing arrangements, work and methods.

469. The areas of technical of support could include but are not limited to the following:

(1) Alternative calculations and studies.

(2) Independent review of licence submissions.

(3) The supply and development of hardware or software tools.

(4) The transfer and development of methodology.

(5) The training of personnel.

ENFORCEMENT

470. Enforcement policy, the enforcement process and the corresponding requirements should be communicated to regulatory staff and implemented by means of enforcement procedures. The enforcement procedures should be reviewed and approved by senior management. To ensure the legal basis is clear the procedures should also receive legal endorsement.

471. In addition to the normal training that regulatory personnel receive, inspectors and other regulatory personnel involved in enforcement should be trained in the overall enforcement process, and the significance of initiating enforcement action.

472. Enforcement decisions should be taken systematically and according to instructions. The process should include a means of confirming that enforcement actions are being applied consistently and objectively from one licensee to another, and that enforcement action decisions take account of safety significance and the seriousness of the violation. Follow-up objectives should be specified and planned, and follow-up action should be carried out.

473. The procedures should specify the prerequisites necessary to initiate enforcement, the formal process itself and the escalation levels of enforcement that are available. The procedures should also specify the responsibilities of those involved.

474. They should also specify how enforcement decisions are communicated to the licensee and what associated authority has been delegated to inspectors and other regulatory staff.

475. The procedures should also cover how instances of non-compliance are to be described and recorded, how they should be reviewed, how an enforcement decision is to be made and recorded, and who should be involved and their responsibilities.

476. Since enforcement is a legal process, the obligations of the licensee should be pursued but their rights should be respected. The time periods allowed to respond to enforcement notices, and the means of appealing them should be communicated to licensee/applicants.

477. Enforcement procedures should include the method for modifying, suspending or revoking licences when it is necessary to do so. Enforcement procedures should also cover failures to comply with enforcement actions. Additional information on enforcement is contained in 50-SG-G4, Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants.

EMERGENCY RESPONSE

478. The regulatory body should ensure that reliable standards for emergency response are available, and ensure that plans and procedures prepared by the licensees are in accordance with them. The plans and procedures should also call for periodic exercises to verify readiness.

479. The plans and procedures should identify the emergencies that regulatory staff should take part in. They should define the roles and responsibilities of regulatory staff during the preparation of emergency plans, during the emergency itself and after the emergency has ended. The regulatory body should ensure these roles and responsibilities are understood by regulatory personnel, by licensee/permit holders, and by other public authorities.

480. Similarly the regulator body should ensure that regulatory personnel are aware of and understand the corresponding responsibilities of licensee/permit holders and of other public authorities. The plans and procedures should define who has the overall regulatory responsibility for emergency planning, resources, training, accommodation and equipment, and what specific regulatory actions are to be performed during the emergency itself, and by whom.

481. The plans and procedures should identify the regulatory staff who constitute the regulator's emergency response organisation. The responsibilities of these units and of individual staff members at headquarters, site, centre of emergency operations, and at other assigned response locations should be described.

482. When the emergency plans have been finalised, they should be communicated to regulatory personnel and used as a training tool to ensure individuals are adequately prepared. The regulatory body should develop procedures for its role in the plan and for interfacing with the external organisations.

483. These procedure should also specify the scope of regulatory responsibility during the emergency and how these activities are activated, and co-ordinated within the regulatory body.

Responsibilities and actions should be defined and described for the different modes of response e.g. normal, standby, activation and deactivation.

484. The procedures should specify an effective means of communication, and of information sharing and transmittal. The methods and the equipment to be used should be included.

485. Protocols should be established for communicating with licensee/permit holders, the public and the media and with government and other public authorities. Reports on performance during emergencies and emergency exercises should be prepared according to specific success criteria, and critically reviewed.

486. Post emergency actions should be defined and carried out. This should include rating the success of emergency exercises to identify areas for improvement. The information from emergencies and emergency exercises should be used for up-dating emergency information and methods, and for periodically reviewing the emergency plan. Additional information on emergency response is contained in 50-SG-G6, Preparedness of Public Authorities for Emergencies at Nuclear Power Plants.

PUBLIC RELATIONS

487. The regulatory body should foster effective lines of communication with interested parties especially the general public, those local to nuclear installations, interest groups, news media, elected and other government officials, employees and licensees/applicants.

488. The unit responsible for conveying information to the public and for acting as the principal regulatory spokespersons should foster and maintain communications links with these parties when significant regulatory activities and decisions are undertaken. This should be accomplished in accordance with defined communications plans.

489. To implement the above, this unit should:

— Plan and conduct active public liaison programs that embrace community, media and government relations. Information materials should be developed and distributed to contribute to better understanding of regulatory activities by the public, licensees and workers.

— Plan, prepare and distribute news releases, notices and announcements. Their issue should be timed to their need and to the particular regulatory activities.

— Develop and maintain an effective internal notification network to ensure regulatory staff keep aware of communicable matters. Periodic reviews should be conducted via inter alia, public awareness surveys and mailing list questionnaires to confirm that communication continues to be effective.

— Maintain a database of information, a ready-use inventory of information materials, and current mailing lists for standing orders of information documents from external sources.

— Be capable of providing information by correspondence, telephone and facsimile or by other means appropriate to the request.

— Provide counselling, coaching and advice, and written material to prepare for communications situations, e.g. public hearings, media interviews, and government committee appearances.

5. ASSESSMENT

GENERAL

501. This section covers the two levels of assessment, Management Self-Assessment and Independent Assessment. When they are conducted, they should provide a thorough, meaningful, and continuing self-examination of the organisation's performance relative to the responsibilities and activities discussed in Sections 3 and 4. These assessments evaluate people, processes and performance.

MANAGEMENT SELF-ASSESSMENT

502. Assessments of regulatory practices should be institutionalised. On a continuing basis, managers at all levels should assess the results their organisational units achieve and how they are being obtained. They should periodically assess their own performance and how it too contributes to meeting objectives.

503. Management self-assessments should be carried out to evaluate known performance issues, to identify contributing management aspects, and to make improvements. Management self-assessments should be conducted to determine the effectiveness of the management process and the results being obtained. They should not be restricted only to establishing that the management process is being followed.

504. The assessments should address broad categories of management issues affecting the manager's unit, such as barriers to good performance, manager-staff communication, manager support to staff, divisional objectives and the mission of the organisation, employee understanding of them, the expectations of those the unit serves, and if the expectations are being met in the most cost-effective manner. Other inputs include upward assessments of managers from their staff.

505. Management problems that hinder the achievement of the unit's and the organisation's objectives should be identified and corrected. Decisions and related actions should be followed up to evaluate their effectiveness.

506. Management self-assessments should be conducted to evaluate the degree to which the manager's unit and the organisation as a whole is succeeding in protecting the public health and safety. Useful insights can be gained from the perceptions of employees, other organisational units and others relative to the following key issues:

(1) Manager Leadership

(2) Strategic Planning

(3) Information and Analysis

(4) Human Resources Development and Management

(5) Control of Performance

(6) Measuring Results

(7) Service Focus and Satisfaction.

507. Additional information on management self-assessment is contained in 50-C/SG-Q5, Assessment of the Implementation of the Quality Assurance Programme.

INDEPENDENT ASSESSMENT

508. Senior management should establish and implement a process of planned independent assessments to measure the regulator's own performance in the basic minimum elements of ensuring that the public health and safety is protected, the effectiveness of the regulator's management system, and to promote improvement in meeting regulatory responsibilities.

509. Senior management should ensure that independent assessments focus on measuring and improving performance. The assessor(s) should act on behalf of, and as advisors to, senior management, and should view senior management as the primary "customer" and the organisational group being assessed as the secondary "customer". Assessor(s) can be internal or external to the regulatory organisation, but they should not be directly involved in the work being assessed.

510. Senior management should ensure that independent assessments of all phases of regulatory activities produce high quality, organisationally meaningful, and professional feedback about the organisation's performance.

511. Assessors should be qualified and performance oriented. The approach they use should incorporate the following concepts:

(1) Obtain factual data, then evaluate.

(2) Perform assessments on activities that make a difference, not trivia with no real impact on organisational performance.

(3) Perform assessments in a manner that emphasises regulatory objectives.

(4) Assessors should not reinterpret or redefine requirements or objectives.

512. Senior management should systematically monitor and track the results from independent assessments and schedule follow-up reviews of areas where line managers need to produce improvements.

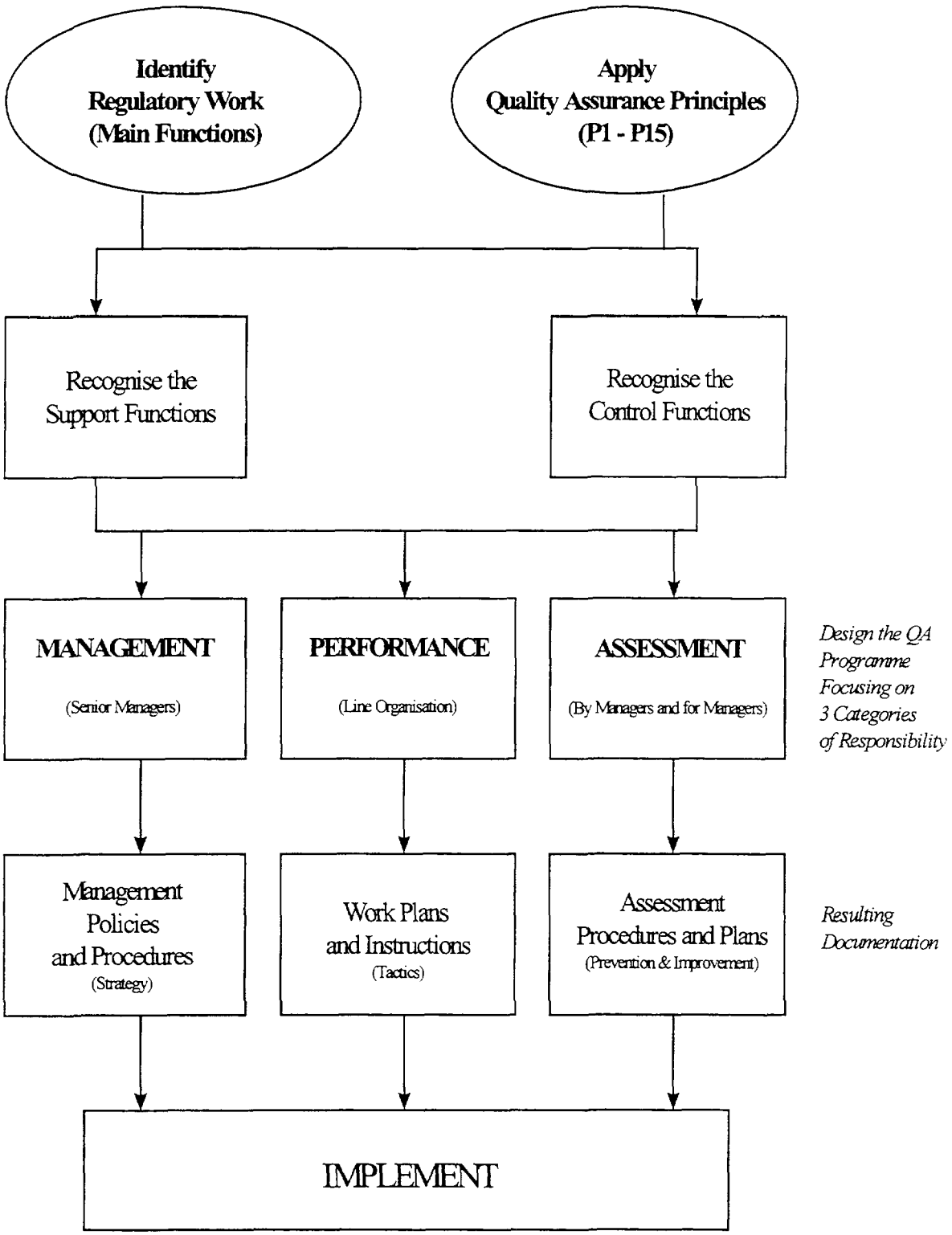
513. Assessment responses from the organisation assessed should identify the cause of the problem, the actions to correct the problem, the actions to prevent recurrence, the lessons learned, and the actions to be taken for improvement.

514. Additional information on Independent Assessment is contained in 50-C/SG-Q5, Assessment of the Implementation of the Quality Assurance Programme.

ANNEXES 1–28

Annex 1

FROM PRINCIPLES TO MANAGEMENT PROCESSES TO PROGRAMME DOCUMENTATION TO PROGRAMME IMPLEMENTATION



Explanation

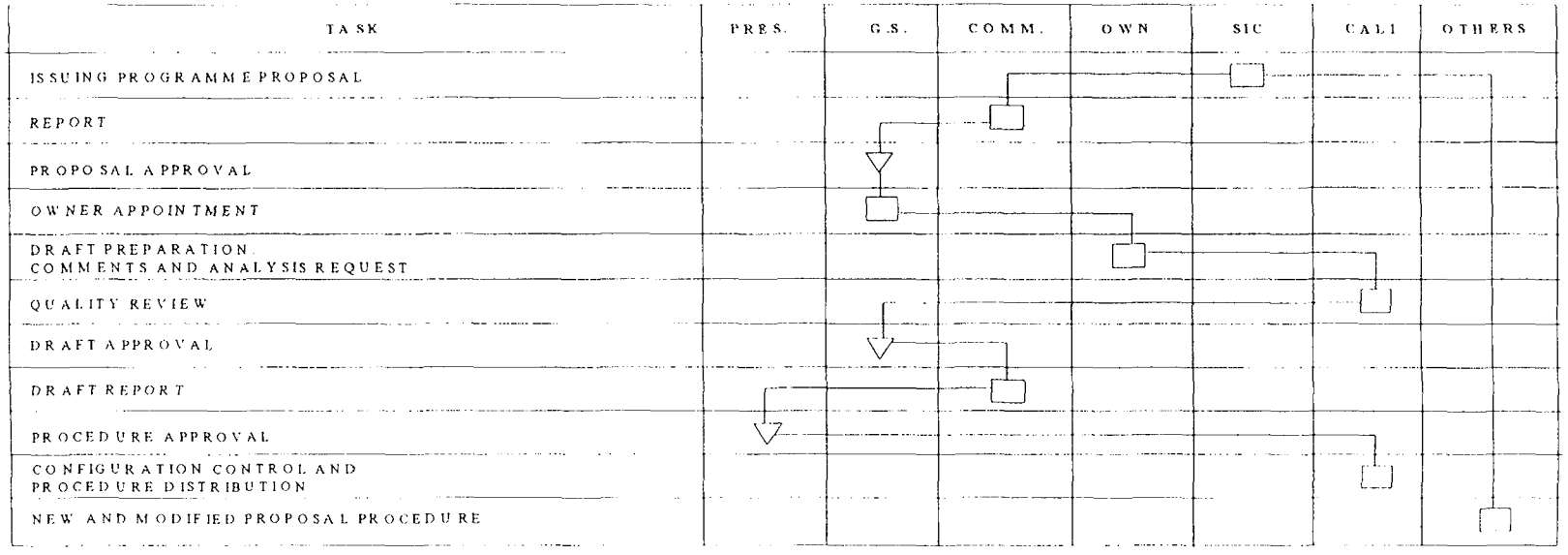
Support functions and control functions derive from the quality assurance principles and the main functions. The support functions set general direction and establish the means and the extent of the overall effort to be applied to the main functions. They enable the right things to be done and the control functions ensure things are done right.

The typical main functions are:	**The support functions are:**	**The control functions are:**
-Regulations and guides	-Manager leadership (P7)	-Work planning and control (P8)
-Review and assessment	-Strategic planning (P2) (P8)	-Organisational factors (P1,P3,P4,P5)
-Licensing	-Training (P6)	-Policies (P2)
-Corrective actions	-Fin/Res/planning/dev (P8)(P6)	-Procedures (P2,P3,P4,P5,P8,P9,P12)
-Inspection	-Experience feedback (P11)	-Service Stds. & monitoring (P10,11)
-Enforcement	-Internal Comm. (P9,P12,P2,P3)	-Communications (P12...)
	-Research and Development (P11)	-Documents and records (P15...)
Some Member States add:		-Management self-assessment (P13)
- Emergency response		-Independent assessment (P13)
- Public communication		-Improvement programmes (P14)

When these functions are distributed into the three general categories of management, performance and assessment, the result will show: (1) the clear involvement of senior managers and well defined responsibilities, and should result in the production of Management Policies and Procedures; (2) the specific activities that the line organization performs to produce the desired results associated with the main functions; (3) the means used to measure and improve performance. This distribution is covered in Sections 3, 4 and 5 respectively.

Annex 2

A FLOWCHART EXAMPLE OF A PROCESS FOR PRODUCING MANAGEMENT PROCEDURES



Annex 3

AN EXAMPLE OF A SET OF VALUES THAT A MEMBER STATE'S REGULATORY STAFF IS OBLIGED TO FOLLOW

- **The rule of legality** requires that the legislation has to be complied with in all regulatory activities. Good knowledge of legislation, duties and authorities is a prerequisite for this principle.

- **The rule of equality** requires that all people, companies and organisations will be treated in an equal manner and that similar matters are solved in the same way.

- **The rule of correct aims** requires that only correct aims, and no other, will be used in human judgement.

- **The rule of relativity** requires that all surveillance activities and sanctions are in correct and reasonable relationship with the matter concerned.

- **The rule of objectivity** requires that staff members of the regulatory body are objective in the matters to be treated. The treatment of a subject shall be transferred to another staff member if the nominated person is involved in the subject for other than regulatory control reasons. An attitude towards the subject that has been made public before treating the subject may influence objectivity.

- **The rule of efficiency** requires that actions are clearly and systematically managed. Financial resources have to be spent and controlled carefully.

- **The rule of openness** requires that regulatory control is public and open-minded, except those ones which are explicitly defined as non-public or secret.

- It is necessary to work in **an atmosphere of confidence and respect**, in order to achieve adequate information transfer for inspection purposes.

- The nuclear safety inspection shall be carried out **in a service rendering manner, but shall be strict and shall promote safety objectives.**

- The staff members of the regulatory body shall be experienced professionals, who shall **continuously assess the quality of their own work and direct their efforts to better performance**.

Annex 4

INDICATORS OF LEADERSHIP SKILLS

The following practices are examples of indicators of leadership skills:

(1) Emphasising the importance of both good technical and management training for all regulatory personnel, and implementing a plan for continuous training;

(2) Making the difficult choice of assigning the best people to key positions;

(3) Promoting people to manager and supervisor positions based on their performance and management skills;

(4) Measuring the commitment of managers and supervisors to good performance by the way they use their time, resources, and people;

(5) Communicating regularly with employees about good performance, good management practices, and improvement;.

(6) Seeking opportunities to speak on good performance and improvement, and describing accomplishments and lessons learned;

(7) Stimulating involvement from all parts of the organization;

(8) Championing the performance and improvement process by regularly reinforcing performance values, co-operation and service between the units of the organisation;

(9) Spending more time identifying the various units of the organization and the service that they give or require from each other, and giving guidance towards developing mutually accepted goals;

(10) Empowering and enabling employees to assume responsibility after ensuring that proper skills and training are in place;

(11) Rewarding, recognising, communicating, and celebrating successes;

(12) Giving ownership of work efforts and process improvements to the staff who are directly involved with them;

(13) Establishing a culture in which mistakes mark pathways for improvement; and

(14) Linking employee performance reviews to the realization of group and organisational objectives.

(15) Creating the optimum working environment for achieving good work on time.

(16) Expediting the resolution of difficult issues and professional differences of opinion.

(17) Leading by example through addressing the principles in para. 206.

Annex 5

BASIC ISSUES ENHANCING SENIOR MANAGER CAPABILITY

1. TAKE RESPONSIBILITY FOR OWNERSHIP

Training needs apply to everyone including managers and senior managers. Only senior managers and managers can change themselves. Many managers find it easier to recognise and analyse the learning needs of others than to evaluate their own developmental priorities. Some are of the view that most of their learning needs are behind them, when, in fact, they are increasing dramatically. No fundamental change is possible in an organization without senior managers and managers themselves changing. Their entry into the change is the signal and approval for others to join in.

2. AGGRESSIVELY INVESTIGATE THE CURRENT REALITY

Many managers rise from out of their technical specialities and need to develop their knowledge and understanding of the various aspects of general management. This, however, only begins to build the base. Effective management goes much further, creating new knowledge, actively probing and exploring the technical, cultural and human realities of the organization. The more rigorous the investigation, the more powerful the learning. The development of senior manager and manager capability requires widening their normal range of debate away from the technical subjects, bringing accepted organisational assumptions to the foreground, and encouraging healthy debate on every aspect of organization and operation.

3. ANTICIPATE THE FUTURE NEEDS OF THE ORGANIZATION EARLY

In today's world of rapid change, the key differentiation between success and failure is the early anticipation of future strategic needs. Senior managers in particular must be able to anticipate changes in the external environment and to reflect on what changes might be required in their own method of thinking and operating. These may include changes in the role of the top management team and its method of functioning, and may even require some of them to be replaced, or other changes in personnel.

4. MAINTAIN A STRATEGIC FOCUS

Training programmes to enhance senior manager capability must have clear strategic objectives. The focus should be on helping the organization realise its operational goals. If this focus is realized, it can also help senior managers recognise what they need to modify in their own behaviour to encourage interdependence in others.

5. INTEGRATE WORK AND LEARNING

While the traditional method to improving managerial capability is the well understood classroom approach, the means to facilitate and increase the rate and the quality of learning on the job holds the greatest potential. Planned job rotation is one method. Another is coaching for senior managers and the selective use of senior managers in the training and mentoring of line managers and staff.

6. CONTINUALLY CREATE NEW PROCESSES APPROPRIATE TO THE ORGANISATION'S ANTICIPATED AND EVOLVING NEEDS

Driven by strategic objectives, managers should seek out innovative approaches based on the culture of the organization and its mandate. It is a dynamic exercise aimed at hitting a continuously moving target. The consequences of new and changing behaviours are not always known at the outset and therefore have to be continually revisited. Although managers should ensure that the operational processes are well established and understood, they should actively subject them to periodic challenges to confirm their continued effectiveness.

7. CONTINUOUSLY IMPROVE THE PROCESSES AND METHODS

Enhancing manager capability is a never-ending exercise. It is an iterative process that focuses on continuous renewal and improvement of management processes and performance, based on the results from feedback. The results are reviewed and the enhancement programme is revised in light of changing needs. Its success is measured primarily by the way senior managers change.

Annex 6

AN EXAMPLE OF A MANAGEMENT INTERNAL POLICY DOCUMENT

STATEMENT ON QUALITY

In defining the policy to be adopted by this organisation regarding quality, we, the undersigned, hereby commit ourselves to the development of a strong quality culture, which underpins the requirement that the organisation shall do everything in its power to protect the public from harmful effects of ionising radiation within its remit.

The object behind the adoption of this culture is to ensure that the organisation as a whole performs its functions effectively and at peak efficiency. We believe that through this approach the performance of the organisation will be able to satisfy the requirements of the state, the public and its own workforce.

We, therefore, undertake to ensure that we will be responsible for:

- Identifying the various components of our overall mission and determining how these will be addressed.
- Determining individual employee responsibilities.
- Aiming to perform each task correctly every time.
- Ensuring the development of the organisation and questioning the way in which it undertakes its duties.
- Introducing improvements.

Achievement of these policy objectives requires all employees to accept individual accountability in executing task requirements and to understand the expectations regarding satisfactory performance.

In committing ourselves to this approach we also undertake to encourage and facilitate the identification of constraints which limit individual and organisational performance, with a view to overcoming these. Likewise, it is essential that all employees commit themselves in a positive spirit to the support of the quality policy goals of this organisation.

Signed:_____ President/Executive Officer

Signed:_____ General Manager/Director General

Annex 7

EXAMPLE OF REGULATORY POLICY TOPICS

General

Application of laws
Security
Materials containing naturally-occurring radionuclides
Designation of personnel as atomic radiation workers (ARW's)
Public and occupational health and safety
Security clearance
Communication
Public meetings
Participation in commissions, inquiries, hearings
Participation in nuclear societies
Public access to information
Relationship with advisory committees
Socio-economic impact analysis
Independence of regulatory staff and conflict of interest

Licensing

Regulatory document production and issue
Categories of regulatory documents
Consultation with other authorities
The medical use of radioisotopes
Particle accelerators
Quality assurance
Emergency plans
Buffer and exclusion zones
Site approval
Public information programme
Applying for a license
Licence conditions
Posting of licences
Nuclear reactors
Inspection and compliance
Enforcement

Environment

Protection of the environment
Environmental assessments

Radiological health and safety

Radiation protection principles
Dosimetry services
Medical records of atomic radiation workers (ARW's)

Transportation

Adoption of IAEA regulations

Annex 8

TYPICAL SUBJECTS COVERED IN A REGULATOR'S STRATEGIC PLAN

- Regulations, standards and guides
- Safety assessment of nuclear facilities
- Fuel cycle
- Medical, industrial and research facilities
- Radiation and dose monitoring
- Emergency preparedness
- Research
- Resource and succession planning
- Institutional, intergovernmental and international relations
- Public information and communication
- Internal management systems

Annex 9

EXAMPLE OF STRATEGIC PLAN CONSIDERATIONS

(1) The plan should be aligned with the regulatory body's mission, vision and core values and should be oriented towards satisfying the public need.

(2) Strategic planning should be integrated with budgeting. The plan should be sufficiently detailed and comprehensive for all organisational units to develop their individual operational goals .

(3) Several types of information should be used in strategic planning. Examples are, feedback from the public and employees, technical, social, and political information and analyses, operational performance data, and other information from licensees and other public authorities.

(4) The strategic plan should make employees aware of how their work contributes to the organisation's overall goals, and how their unit's goals align with the organisation's goals.

(5) Improvement goals should be among the top strategic priorities. This should be evident by the extensive resource allocation including education/training, software, tools, and support services.

Annex 10

AN EXPLANATION OF SERVICE STANDARDS

The service that one unit of the regulatory body provides to another may be well recognised by all regulatory body staff. For example, the safety evaluation division provides a safety review and assessment service to another division such as the licensing division. Another example is the training division providing training to all divisions. In both cases the general service is evident, but what's not so well known are the things that make up those services. What is the total service capability? What lead time is necessary for delivery? How long will it take to provide the service? How frequently will it be provided? What can people do if they are not satisfied with the service? The role of service standards is to answer these questions. The shortened form of standards of service is 'service standards'.

Service standards let one organisational unit know what *kind* of service they can expect from another. They also equip the service providers with a clear sense of direction. Standards that set out the goals of a service and what it consists of, act as a guide that defines the type and quality of performance expected. Service standards are best developed when they are established in consultation with the staff who must meet them.

Characteristics of good standards

Standards that play an effective role in delivering better service are:

- **Meaningful to clients.** Standards should reflect those aspects of the service that the clients feel are important.
- **Developed in consultation with staff and clients.**
- **Clearly communicated.** It is important that staff and clients are aware of the exact standard that will be worked to and delivered.
- **Challenging but attainable.**
- **Measurable.** Service performance is measured and reported. This provides a means of identifying the strengths and weaknesses of the service and points to changes that can further improve the service.
- **Reviewed regularly.**

Developing service standards

There are six basic steps involved in developing service standards.

1. **Know your operation:**
   - Identify your clients;
   - Identify your services;
   - Identify your partners;
   - Know what you are doing now; and
   - Know what you are capable of doing with the resources you have.
2. **Consult with your staff and clients.**
3. **Set client-sensitive service standards.**

4 **Empower and train service providers.**

5. **Communicate service standards and report on performance.**

6. **Manage the unit based on service standards and service quality.**

Annex 11

EXAMPLES OF DELIVERY TARGETS IN A SERVICE STANDARD

The delivery targets for the service that one organisational unit of the regulatory body provides to other units within the organisation should be stated. If the regulatory body consists of more than one authority, this kind of arrangement can help ensure work is properly coordinated between them. It is also useful for organisational units that provide the supporting functions to include similar performance commitments to the units they service. Delivery targets may be qualitative or quantitative. Not all of these will apply in every case, nor is this list complete. The list provides only a starting point for discussions between the unit delivering its service and the unit that receives it.

Accessibility:

- Staff will be available Monday to Friday from x hours to x hours.
- We will reply to your e-mail enquiry within x hours.
- We will provide a competent alternate person to respond to your request should the primary person be unavailable.
- Copies of checklists and rough notes will be available on request.
- Others as appropriate.

Reliability:

- The quality of our work will be assured through the systematic application of approved procedures.
- We will require x hours/days/months lead time to deliver a satisfactory product.
- We will obtain the services of a contractor should we lack the in-house capability.
- We will ensure our contractors are competent and are familiar with the agreed protocols.
- Others as appropriate.

Responsiveness:

- We will acknowledge your request and keep you informed of changes in our work priority.
- Without compromising existing commitments, we will make every effort to respond to unforeseen requests.
- Others as appropriate.

Thoroughness:

- We will plan our work activities and discuss the details with you including scope of work, schedules, reporting methods, staff to be assigned to ensure the coverage is complete.
- Our work will be checked for accuracy and completeness before release.

- Others as appropriate.

Timeliness:

- We will provide the service within x days.
- We will provide a schedule outlining when you can expect a response within x days.
- We will perform continuing checks every x days/months/years.
- Others as appropriate.

Transparency:

- Upon request we will provide you with details of work methods and intermediate results.
- Details of work status will be available on the work management system.
- We will keep you informed of discussions we have with internal and external groups.
- We will cc you on copies of correspondence.
- We will produce and circulate minutes of the meetings we initiate with interested parties.
- We will provide you with a draft copy of our report before finalizing it.
- Others as appropriate.

Others:

- As appropriate.

Annex 12

A TYPICAL FINANCIAL PLANNING CYCLE

(1) Priority Setting: Develop strategies and action plans that specify how the regulatory body is organised and how it will utilise its resources in the near term and long term.

(2) Planning: Establish detailed action plans that align with the regulatory body's strategic objectives. Set priorities. These planning steps require input from managers and their acceptance of the plans that follow, as well as co-ordination an co-operation between functional areas of the organisation. Those who will be held accountable for implementing these plans should participate in their preparation.

(3) Budgeting: Decide which action plans should be funded and how e.g. by licensing fees, foreign assistance fees, consulting fees, appropriations. The kind of resources, their quality and quantity should be identified for each planned activity. The appropriate cost for them should be applied and the total cost should be calculated. Performance should be measured against these estimates.

(4) Budget monitoring and control: Monitoring is measuring performance relative to the work plans and budgets. The appropriate factors for measuring performance should be chosen. What data, when it is required, from where it should be obtained, by whom, and for whom, and the accuracy of the information should be identified. The data should be processed accurately and results should be reported quickly. Managers should review the financial results regularly and redirect resources if required. Problems and deviations from plans should be identified. Methods of follow-up and intervention should be specified and used.

(5) Reporting: Each level of management with financial responsibility and accountability should report on their performance. This is necessary for continued operational and strategic planning updates.

Annex 13

HUMAN RESOURCE DEVELOPMENT

A programme to create human resource development opportunities and retain staff in the organisation should be implemented by line managers. It should be integrated into routine work planning and performance using, for example, the following methods:

(1) Using special projects and supervisory step-ups to fulfil the roles and responsibilities of an absent supervisor.

(2) Identifying the pool of junior staff and the relevant positions they will be rotated through for a period (2 or 3 years) before they are assigned to a position in a particular area.

(3) Establishing dual career paths for individuals who are essential, and perhaps irreplaceable, allowing them to progress without moving or having to wait for managerial positions.

(4) Establishing an effective mentoring process to guide people in their career choices. Mentoring would require training, support and management recognition.

(5) Using evaluation tools such as assessment of critical staffing positions, environmental scanning methods, and operations-to-human resource needs assessment for succession planning and career development activities.

(6) Supporting and arranging employee exchange programmes.

(7) Increasing participation in project teams.

Annex 14

CONSIDERATIONS FOR AN EFFECTIVE APPROACH TO TRAINING

To approach training systematically, the following considerations should be evaluated:

(1) Entry level to the organisation and transfer orientation.

(2) Cost benefits and alignment with organisational objectives.

(3) Responsibilities e.g. overall programme design and delivery, organisational unit responsibility, individual staff responsibility.

(4) The need or not of a training department.

(5) Current, short term, and long term training needs.

(6) The facilities and the functional areas being regulated.

(7) The need for generalists and specialists, their academic qualifications and experience.

(8) Core training subjects that will cover a broad range of regulatory activities.

(9) The specific technical, management, legal, public information and personal skills training needed.

(10) The displacement effect of training on the availability of regulatory staff.

(11) Screening of trainees.

(12) Planning, preparation, review, scheduling and delivery.

(13) In-house, and consultant instructors, their qualifications and training techniques.

(14) Training programme design i.e. classroom, on-the-job, secondment, self-study, basic material, job specific, advanced, refresher.

(15) Testing requirements.

(16) Evaluation of success of training programmes based on e.g.

- the knowledge acquired (examinations, demonstration, job performance)
- the quality of teaching (instructor competence and skill, teaching techniques)
- pertinence
- results from monitoring delivery
- meeting agreed expectations.

Annex 15

AN EXAMPLE OF A TRAINING AND DEVELOPMENT PLAN (STRATEGIC)

1. Introduction

This section covers:

1.1 The organisation's commitment to training in several forms supported by the allocation of funds.

1.2. The main purpose of the plan relative to:
a) recognition that the training plan's purpose is to support the delivery of main regulatory functions;
b) identifying overall training objectives and strategic direction;
c) forecasting training activities and projecting their cost;
d) evaluating the plan's performance.

2. Operational Context

This section covers the operational justification for the training needs relative to the regulator's responsibilities and its current priorities and nuclear safety. The two main areas that are addressed are technical and scientific factors, and organisational and other factors.

3. Support to the current year operating plan

This section links the training plan to objectives identified in the current operating plan.

4. Training and development objectives

This section identifies the overall objectives that will be satisfied. It refers to the training for managers and staff in the skills needed to support the delivery of the regulatory mission. These may be technical and scientific skills, management and leadership skills, or administrative support skills.

5. Projected demand and training costs

This section and the supporting schedule identifies the specific training subjects that will be offered during the current year and their projected costs and budget constraints. The priority training subjects are listed. The method of delivery is specified.

6. Other development activities

This section discusses other means of training that can be planned and costed. These include:

- attendance at conferences
- job shadowing
- on-the-job training
- inter unit attachment
- mentoring
- external attachment

7. Evaluation

This section refers a formal cost/benefit review of the training plan. This will include the mid and year end formal reviews, and two less formal quarterly reviews. It describes how Divisions/Units will perform the reviews, and indicates that the results and recommendations will be reviewed by senior management.

Annex 16

AN EXAMPLE OF A TRAINING PROGRAMME (OPERATIONAL)

1. Overview

A comprehensive and systematic education and training programme is important to develop a high level of regulatory expertise. It is also essential for developing and retaining the level of staff capability and competence necessary to tackle safety related issues effectively. This training programme was designed and organized into four levels according to the expertise of the organization's staff. The four levels are Fundamental, Intermediate, Advanced and Expert. The training for these levels is given continuously step- by-step from the fundamental level to the expert level.

2. Programme

2.1 Fundamental level — basics of nuclear regulation
Classroom training and on-the-job training at an NPP site for a period of 1 month

Course subjects
Function & mission
- Organization
- Administration system
- Reviewers and inspector's attitude

Introduction to nuclear energy
Introduction to nuclear power plant systems
Introduction to radiation protection
Introduction to quality assurance
Introduction to nuclear energy
Introduction to nuclear power plant systems
Introduction to radiation protection
Nuclear regulation
Codes & standards

2.2 Intermediate level — regulatory practice
Two weeks of classroom training and 4 weeks of on-the-job training.
Assign to the resident inspectors office at the NPP for a 2 year period
Simulator training
Overseas OJT assignment through IAEA fellowship programme and/or internal self-training programme for 6 month to 1 year period.

Course subjects
Attitude as a regulator
Atomic energy laws
Nuclear regulatory systems and processes, policies and application
Quality assurance
Codes & standards
Construction phase training
- Introduction to the PSAR for specific plant
- Introduction to the design concepts

In-Service training
- Pre-operational stage
- Operating stage
- Radiation safety

2.3 Advanced level

Development of regulatory expertise in:

- Reactor safety/engineering
- PSA
- Quality assurance auditing
- Analysis of environmental sampling; gamma nuclides,
- Radiation measurement
- Management of R&D project including international co-operation

Management also encourages the staff to obtain advanced university degrees to help with the development of technical skills.

Course Subjects

Regulatory policy
Reactor safety engineering
Probabilistic safety analysis
Analysis of environmental samples
Radiation measurement
Management of R&D projects

2.4 Expert level

The following are examples of courses that are being developed to cope with future licensing demands.

Course subjects

Analog and computer-based digital instrumentation and control system.
QA lead auditor training.
Environmental qualification of equipment for harsh operating conditions.
Human factors and human reliability analysis.
Nuclear policy, regulatory policy and regulatory system
Life extension and ageing management of nuclear power plant components.
Advanced non-destructive examination, performance-based qualification, and risk based inspection.
Pump and valve in-service testing.
Technical specification conversion review support
Instructional infrastructure support
Computer software in reactor control and reactor protection systems.
Safety analysis programmes including unreviewed safety question.
Performance indicators and assessing performance.
Maintenance programme.
Nuclear fuel design analysis and safety reviews.
Probabilistic risk assessment, nuclear risk management and risk-based regulation
Advanced thermal-hydraulics
Common cause failure data collection and analysis
Operator licensing programmes
Conduct of operations
Review of quality assurance programmes
Configuration management
Integration of safety culture into safety assessment
Operational readiness
Radiological control programmes
Welding inspection and RT film review

Annex 17

MANAGEMENT TRAINING SUBJECTS

Training managers and measuring their performance should be an ongoing continuous programme. It should be an iterative process that focuses on renewal and improvement based on the feedback of results. Success should be measured primarily by the way managers change. The following are examples of management training subjects.

Leadership training

To describe for managers the role of the leader in a performance oriented culture.

Good management and management systems

For managers and their immediate staffs on getting started with the application of good management practices.

Strategic planning and good management practices

Shows the relationship between strategic planning and the application of good management practices.

Basic training in good management practices

Provides a comprehensive understanding of the analytical and behavioural aspects of good management. Explains plan, do, check, act, basic process improvement concepts, planning, and new behaviours necessary for success.

Seven habits of highly effective people

Fosters personal behaviours which will allow managers to understand and be successful in an open, interactive, performance oriented culture.

Managing change

To describe to managers the dynamics of organizations and individuals in a changing environment and how to manage it.

Management self assessment

For managers and supervisors on how they can determine how well they are providing the leadership to enable their staff to continuously meet client and organisational objectives and expectations.

Conducting effective meetings and communicating effectively

Identifies various types of meetings informal, formal, for information, operational meetings, planning meetings, analytical meetings etc. and describes how they should be managed. How to communicate effectively with immediate staff, up and down the organisational chain and across organisational lines.

Project management

Introduces managers to the key factors which are necessary for the successful completion of projects. Delivery costs and techniques for maximising the use of resources and monitoring progress are discussed.

Performance measurement and work scheduling

Explains the difference between performance measures and activity measures and the different approaches to measure both. Describes what it is and not how to do it.

How to manage client relations

Describes to managers and staff the fundamentals of service, including defining clients, establishing and maintaining feedback mechanisms, forming partnerships, dealing with problems.

Overview on client relations

Introduces senior managers to client relations to in order to give them some context for what their managers should be doing following their training.

Independent assessment

Describes to managers what constitutes independent assessment, the concepts and why it is done.

Annex 18

AN EXAMPLE OF INTERFACE NORMS

Good communication is essential to have confidence that the desired result will be achieved. The regulatory body has to communicate well internally and externally in the interest of safety. The following norms can be used as a basis of interaction internally between organisational units, and externally between regulators, between regulator and licensee and between regulator and other interested parties. They can be particularly useful for governing the conduct of meetings and for arriving at important safety decisions.

1. Participate openly and encourage open participation of others

Open communication is critical to understanding another's position or to solving a problem. It begins by communicating openly yourself.

2. Be hard on the issues, soft on the people

Open communication sometimes means disagreement. Disagree with facts and ideas, and be hard and critical of issues, not of the person presenting them.

3. Listen and question to understand

Listen past the first few words that are spoken. Have a questioning attitude. Focus on the speaker and ask questions to ensure understanding and to better develop facts, ideas, and positions.

4. Check your assumptions

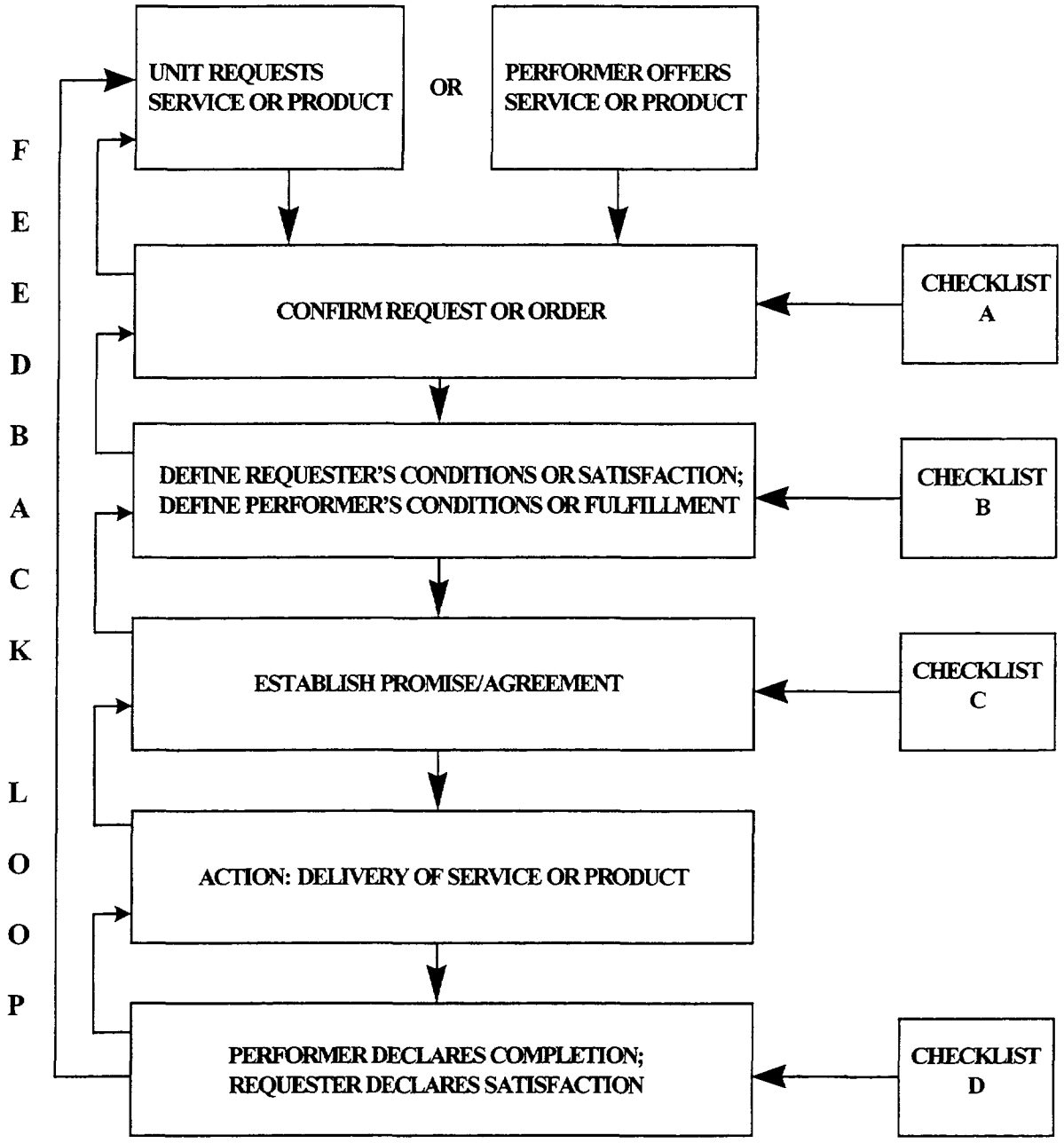
Are your assumptions correct? Collect the facts, question people, and check them out before acting. Or, be aware that the position/action you are taking is based on assumptions not facts.

5. Consider the possibility that you may be wrong

No one is right all the time. Listen actively, question constantly, and check fully.

Annex 19

AN EXAMPLE OF A COMMUNICATION MODEL



The communication model divides communication into a number of steps. This enables persons to be aware of the communications that should take place in order to minimise the number of unchecked assumptions. The net result will be improved interaction and increased satisfaction with the service received.

Requester is the person or organisational unit that requests a service or product, or who accepts an offer of a service or product, from a **performer.**

Performer is the person or organisational unit that acts on a request for a service or product, or that offers a service or product to a **requester.**

Annex 20

AN EXAMPLE OF AN AGREED COMMUNICATIONS PROTOCOL

1. Objective

This protocol identifies processes governing communication between the regulatory body and licensee A. Written and verbal communications between the two organisations can occur at all levels on a routine basis. To ensure communication is effective and to minimise misunderstanding, the various levels of communication, from official to unofficial levels, and the associated governing rules must be clearly defined and accepted for use by both organisations.

2. Operating principles

2.1 Formal communication will be conducted according to Table 1. Where warranted communication may be at higher levels.

2.2 Additional temporary links may be agreed in writing to deal with specific topics.

2.3 Appropriate informal communication aimed at clarifying issues, is required and encouraged.

2.4 The distribution of communication within each organisation is the responsibility of that organisation.

3. Levels of communication

3.1 A protocol is established for convening meetings.

3.2 For each level of communication, the level of formality, the initiators, the communication forum, the purpose, and the rules of engagement are provided.

3.3 The following definitions are intended to clarify the different levels of communication:

An *official communication* conveys commitments, requests or positions of either organisation. Documentation of *official communications* is required and is filed.

An *unofficial communication* conveys commitments, requests or positions by individuals which are not binding on either organisation. *Unofficial communication* if documented need not be filed.

A *formal communication* indicates that a written record of the communication is prepared. This documentation may be *unofficial*.

An *informal communication* indicates that no written record of the exchange is required.

LEVELS OF COMMUNICATION

	Formal	Informal
Official	Level 1	N/A
Unofficial	Level 2	Level 3

Table 1. FORMAL COMMUNICATION BY SUBJECT

Subject	Regulatory contact	Licensee contact
Facility Licences	President Licensing Director	General Counsel
Appearance before Reg. Commission	Secretary General	General Manager
Issues affecting more than one facility	Licensing Director	General Manager
Facility-specific issues	Senior Facility Representative	Facility Director
Safety analyses	Director Safety Evaluation	Division General Manager
Operator training and authorisation	Director Operator Certification Division	Facility Director
Generic radiation protection matters	Director Radiation Protection Division	General Manager
Approval Of staff positions	Director General of Licensing	Facility Director
Quality assurance matters	Director Performance Evaluation Division	Facility Director

An Example of Level 2 Communication

Nature: Formal and unofficial

Initiator: ***Regulator***
- Senior facility representative/subject matter section head or delegate

Licensee
- Subject matter superintendent or delegate

Forum:
- meetings
- correspondence

Purpose:
- consultative discussions on developing or pending positions
- review status of licensing issues

Rules:
- positions stated, requests made and actions accepted are unofficial unless confirmed by Level 1 communication protocol
- meeting discussions are minuted and distributed to attendees and appropriate organisational positions

Subject examples:
- technical review on action items
- review/discussion of plans and schedules for completion of outstanding action items
- technical discussions on pending position

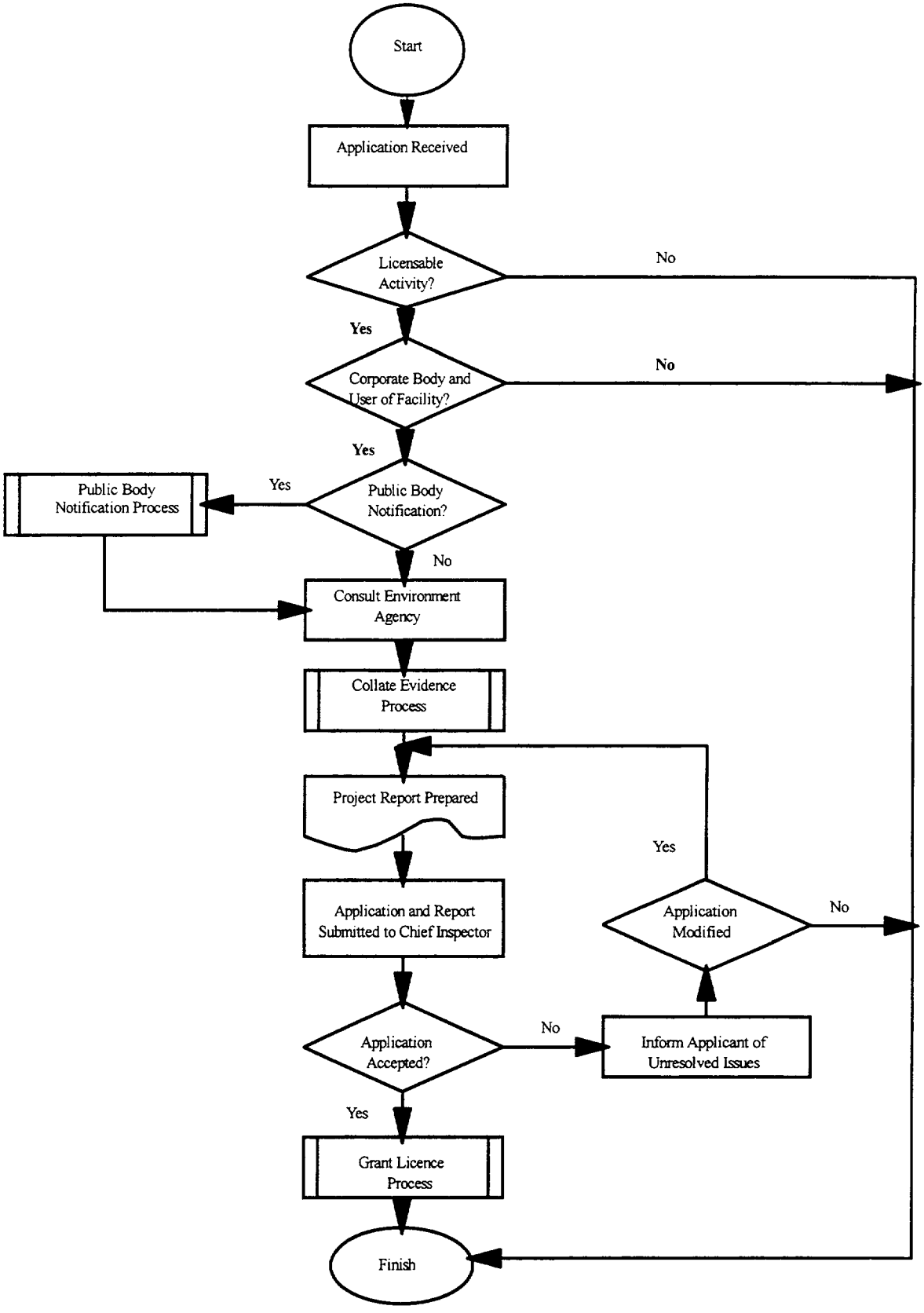
Annex 21

EXAMPLE OF AN AGREED NUCLEAR SAFETY ISSUE RATING SCALE

Category	Issue description	Characteristics of issue	Characteristics of licensee response
1.	Potential	-Risks judged to be not acceptable -Priority not established	-Information only -Informal
2.	Emerging	-Risks judged to be potentially larger than normally assumed -Absolute risk acceptable -Low priority	-Verbal/e-mail (informal) -Min. effort to define issue -Response time approx. months -Inform regulator informally
3.	Significant	-Risks judged to be larger than normally assumed -Absolute risk considered acceptable -Medium priority	-Written (formal) -Develop L1 Action Plan -Response time-months -Resources assigned -Responsible line organisation notified for information -Regulator(s) informed in writing. -Commit to action plan
4.	Major	-Incremental risk known to be large -Absolute risk is known to be acceptable -High priority	-Written (formal) -Develop detailed action plan -Resources dedicated -Licensed staff notified -Regulator(s) informed in writing; basis of risk evaluation given -Duty Manager notified
5.	Diligence	-Absolute risk still acceptable but near unacceptable levels -Very high priority	-Written (formal) -Project oversight established -Dedicated resources assigned -Develop risk management plan -Develop detailed action plan -Licensed staff informed in face-to-face meetings -Regulators formally notified in writing -Safety committee meeting -Effectiveness review
6.	Stop work	-Absolute risk above acceptable levels -Urgent priority	-Duty Manager and Operations Manager notified immediately -Operation placed in safe state -Regulators notified immediately -Recovery plan initiated -Corporate organisation notified

Annex 22

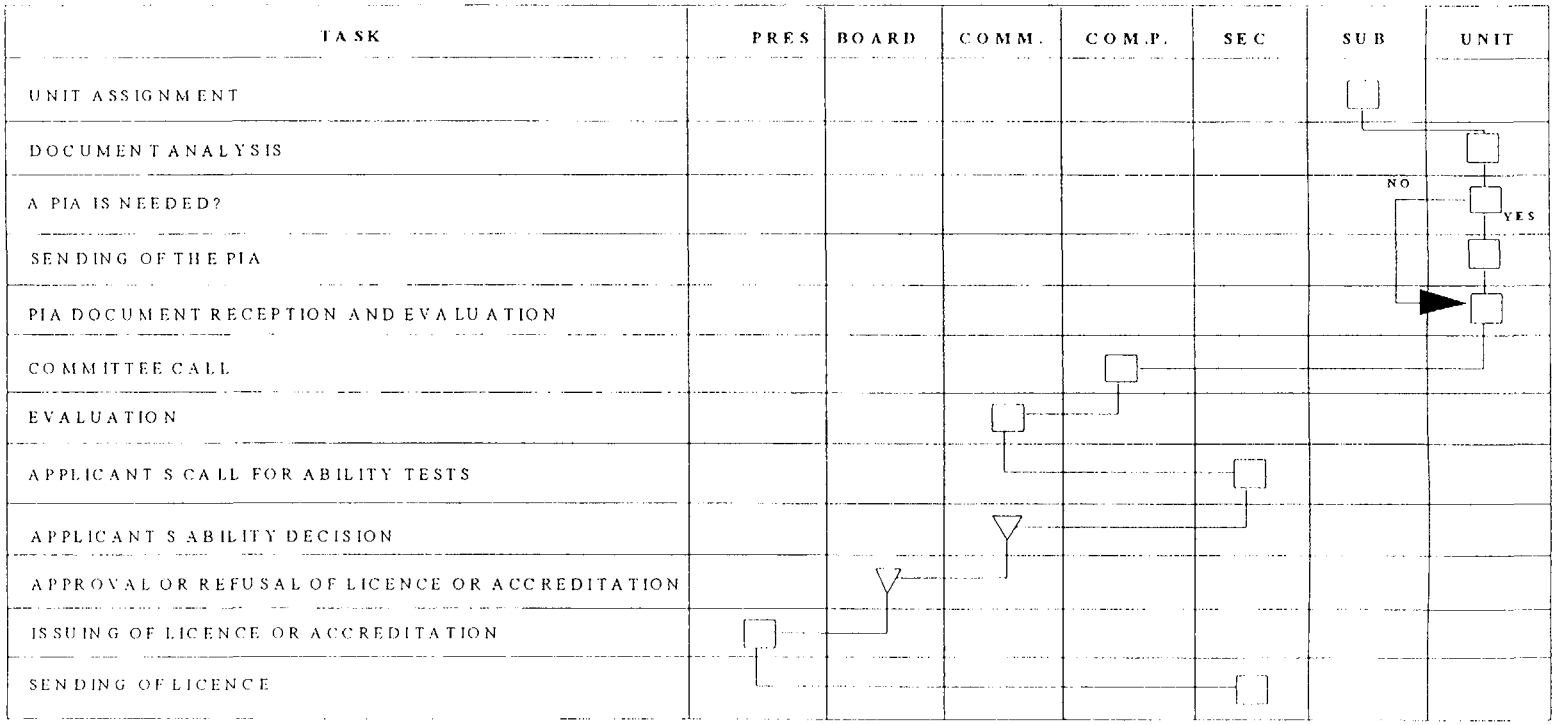
AN EXAMPLE OF FACILITY LICENSING PROCESS



Annex 23

AN EXAMPLE OF AN OPERATOR LICENSING PROCESS

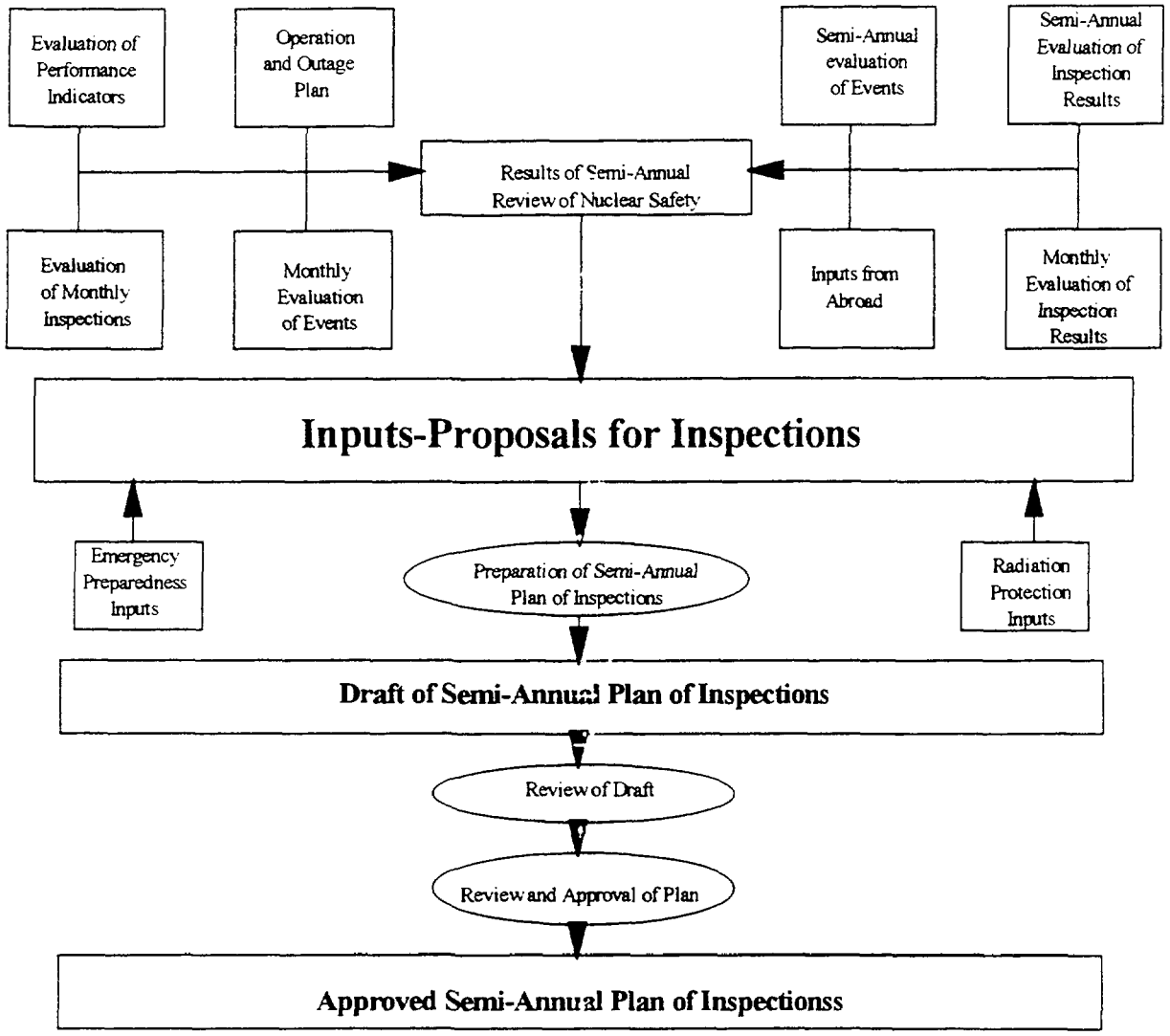
FLOWCHART PROCESS FOR GRANTING OPERATOR LICENCE



Annex 24

AN EXAMPLE OF PLANNING INSPECTION ACTIVITIES

Planning of Semi-Annual Inspections



Annex 25

TYPICAL PRODUCTION PROCESS FOR REGULATORY DOCUMENTS

(1) Planning

Proposal

- The purpose, scope, rationale, audience, reviewers, schedule and estimated cost should be stated in the proposal.
- When the proposal is accepted, resources should be committed.
- The corresponding responsibilities should be specified.

Specification

- Upon acceptance of the proposal, it should be expanded and a detailed specification should be produced.

Production plan

- A detailed plan indicating the production, consultation and review process should be prepared.
- Milestones and resources should be included e.g. preparation of first draft, technical review, legal review, public and licensee consultation, review of comments, documenting decisions, finalisation of draft, submission for approval.

Production approval

- The proposal, the specification and the production plan should be approved.
- Approval should mean a commitment of resources to the overall process.
- Approval indicates the weight of authority behind the project.

(2) Writing

- Research, identify and assemble all background and supporting information.
- Produce first draft according to specification.
- Confirm that existing proposal is still applicable or propose changes.

(3) Review

- Circulate document to pre-selected reviewers.
- Technical reviewers should comment on technical accuracy.
- Legal reviewers should comment on legal aspects.
- Incorporate comments.
- Validate revision against specification and proposal.
- Prepare external mailing list and review for completeness.
- Circulate revised document for external consultation.
- Review comments and amend document

- Submit for approval; identify public concerns and issues that were hard to resolve.

(4) Production

- Send out according to mailing list.

Post mortem

- Meeting of drafters to devise ways of improving.

Revision Period

- Specify period for next formal review and conduct review.

Archiving

- Follow specified requirements.

Annex 26

EXAMPLES OF CLASSES OF REGULATORY DOCUMENTS

- Regulations
- Regulatory policy
- Regulatory standard
- Regulatory guide
- Regulatory notice
- Regulatory procedure

A regulatory policy describes the philosophy or fundamental factors that direct regulatory actions and guide the conduct of persons subject to regulatory requirements, as well as others who interact with the regulatory process.

A Regulatory Standard describes detailed specifications, criteria or actions that can be objectively measured; are acceptable to the regulator as meeting regulatory requirements; and are suitable for incorporation into licences.

A regulatory guide describes criteria or actions that the regulator accepts and recommends as meeting regulatory requirements, but which are not suitable for incorporation into regulatory licences.

A regulatory notice provides case-specific advice and information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.

A regulatory procedure describes the work processes that the regulator follows.

Note: This is an example of one member state's approach to the classes of regulatory documents it uses. There are other approaches depending on the degree of prescriptiveness used by the regulator.

Annex 27

CATEGORIES OF REGULATORY DOCUMENTS

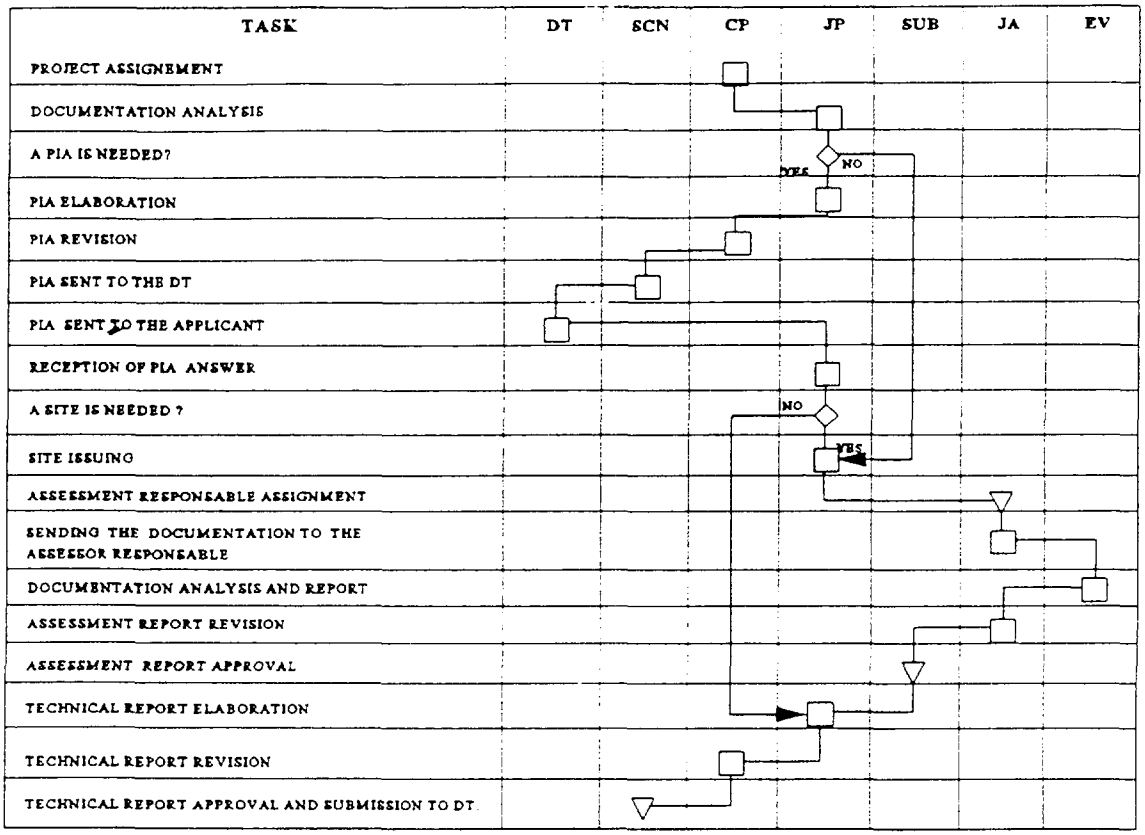
(Siting, Design, Construction, Commissioning, Operation, Temp. Shutdown, Licence Renewal, Decommissioning)

CAT 0	General and Corporate
CAT 1	Nuclear Power Plants
CAT 2	Non-Power Reactors
	Research Reactors
	Test Facilities
CAT 3	Fuel Cycle Facilities
	Mines and Mills
	Tritium Removal
	Fuel Fabrication
	Material Processing
	Waste Management
	Waste Storage
CAT 4	Substances and Devices
	Industrial Radiography
	Gauges
	Borehole Logging
	Nuclear Medicine
	Lab Research
	Cobalt Therapy
	Particle Accelerators
CAT 5	Export and Import
CAT 6	Examination and
	Certification of Personnel
CAT 7	Site, Environment and
	Disposal of Waste
CAT 8	Occupational Health and Safety
CAT 9	Physical Security
CAT 10	Safeguards and Non-Proliferation
CAT 11	Transportation
CAT 12	Finance and Administration
CAT 13	Training
CAT 14	Safety Assessment

Annex 28

A FLOW CHART EXAMPLE OF A REVIEWING AND REPORTING PROCESS

ISSUING NPP TECHNICAL REPORT



DECISION

ACTIVITY

OPTION

DT: TECHNICAL DIRECTOR

SCN: NPP DEPUTY DIRECTOR

CP: PROJECTS COORDINATOR

JP: PROJECT HEAD

SUB: DEPUTY DIRECTOR

JA: BRANCH HEAD

EV: EVALUATOR

"PIA": ADDITIONAL INFORMATION REQUEST

"SITE": ASSESSMENT REPORT REQUEST

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2–6 March 1998, Vienna, Austria