GUIDANCE DOCUMENT

FOR

STREAMLINING THE

HIGH-LEVEL WASTE PROGRAM

DIVISION OF WASTE MANAGEMENT

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

January 8, 1999

1.0 HIGH-LEVEL WASTE PROGRAM

The high-level waste (HLW) program has many unique qualities or activities that separate this one of a kind licensing action from other types of licensing actions conducted by the U.S. Nuclear Regulatory Commission (NRC). Specifically, the Nuclear Waste Policy Act of 1982 (amended 1987) (NWPA) requires early pre-licensing consultation with DOE, adoption of technical criteria by rulemaking, inclusion of NRC's comments on sufficiency of site characterization and waste form in DOE recommendation of Site Suitability, authorization for repository construction, operation and final closure, and a licensing decision within 36 months (including adjudicatory hearings). In addition, Congress is expected to request NRC's comments on DOE's Viability Assessment which is a DOE management tool that will provide a basis for making an informed assessment of the feasibility to proceed with the process of licensing and constructing a repository at Yucca Mountain (YM) based on a current understanding of a preliminary design concept, system performance, a plan leading to the License Application (LA) and cost to develop and operate a repository. Nevertheless, there are aspects of this licensing action that are very similar to other agency licensing actions, for example, the regulatory philosophy, the development of Safety Evaluation Report or Requests for Additional Information (RAIs), and to that extent the HLW program should adopt similar guidance.

Existing NRC regulations at 10 CFR Part 60, issued in 1983, contain generic criteria governing the licensing of the Department of Energy (DOE) to receive and possess source, special nuclear, and byproduct material at a geologic repository sited, constructed, and operated in accord with the NWPA. Since their issuance, new legislative direction, extensive site-specific performance assessment experience at YM, and the results of systematic analysis of the Part 60 requirements have resulted in fundamental changes to the technical assumptions and knowledge of post-closure repository performance upon which the existing criteria were founded. As a result, the NRC staff has proposed new site specific, risk-informed, performance-based regulations, 10 CFR Part 63, which when final will be the criteria upon which the licensing of YM will be based. The proposed 10 CFR Part 63 follows the recommendations of the National Academy of Science and establishes an all-pathways dose standard. Until the time that proposed Part 63 becomes final, however, the technical criteria are contained in 10 CFR Part 60.

As with the licensing process, the NRC role in the Environmental Impact Statement process is also unique for the high-level waste repository at YM. NWPA gave DOE the primary responsibility for preparation of the for the YM repository in accordance with National Environmental Protections Act (NEPA). In preparing the EIS, DOE is not required to consider the need for the repository or nongeologic alternatives to the site. Under NWPA, the NRC is to adopt the EIS to the extent practicable. The protocol for NRC staff review and adoption of the EIS has been described in the *Federal Register* (Draft Rule - May 5, 1988 53 FR 16131 and Final Rule - July 3, 1989 54 FR 27864).

The purpose of this document is to provide staff in the HLW program with guidance that can be used to help them ensure the application of a consistent, effective and efficient regulatory program. This guidance will supplement existing guidance principally contained in Regulatory Guides (Reg Guides), Acceptance Criteria and Review Strategy of the Issue Resolution Status Reports, and YM Review Plan (YMRP) scheduled for initial development in FY1999. Rather, it

is intended to ensure that reviewers conduct their reviews, including the application of Reg Guides, Acceptance Criteria and YMRP, consistent with the NRC's fundamental regulatory framework.

A review of any licensing action is not intended to be a exhaustive evaluation of all aspects of the repository. Specific information about implementation of the program outlined in an application is obtained through the NRC review of procedures and operations done as part of the inspection function. The detailed steps of a licensing review are discussed later in this guidance.

2.0 REGULATORY PHILOSOPHY

Streamlining and NRC's Safety Philosophy

Since the Atomic Energy Act of 1954 was passed, the Commission has been engaged in a continuing process of interpreting and applying the agency's basic responsibilities as defined by that law: viz., to "protect public health and safety," "assure the common defense and security," "minimize danger to life or property," and "provide adequate protection." These terms are not defined in the AEA, nor are they self-explanatory. The basic NRC Safety Philosophy is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

> "LICENSEE RESPONSIBILITY embodies the principal that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing, and other activities on those areas where the need, and the likely safety and safeguards benefit, are greatest."

To state it more succinctly, the safe operation of any nuclear facility is the responsibility of the licensee. This philosophy is an important foundation for how NRC staff is to conduct their reviews in general, and streamlined licensing reviews in particular. Streamlining begins with a recognition of NRC's regulatory role in relation to its licensees, i.e., that licensees have the primary responsibility for ensuring the safety of nuclear facilities.

Implementing this philosophy, means the following:

- NRC does not select sites or designs or participate with licensees or applicants in selecting proposed sites or designs.

- NRC's role is not to monitor all licensee activities but to oversee and audit them. NRC should evaluate whether the proposal meets the applicable regulations based on a review of what is in the application. Staff audit calculations should be used in very limited situations such as unique proposals involving new methods or assumptions. Otherwise, the NRC staff should review the application to ensure that assumptions are justified, methods used are acceptable and applicable over the range presented in the application, the model was properly applied, and the results are acceptable. Staff can and should do quick, bounding calculations; however, in-depth, detailed performance assessments can be limited to a very few applications. Figure 1 shows the relationship of the level of detail to licensing reviews and inspections.

- The three outcomes available to NRC at the conclusion of a licensing review are: (1) grant the application; (2) grant the application subject to certain conditions agreed upon by the licensee; or (3) deny the application. Other than rejecting an

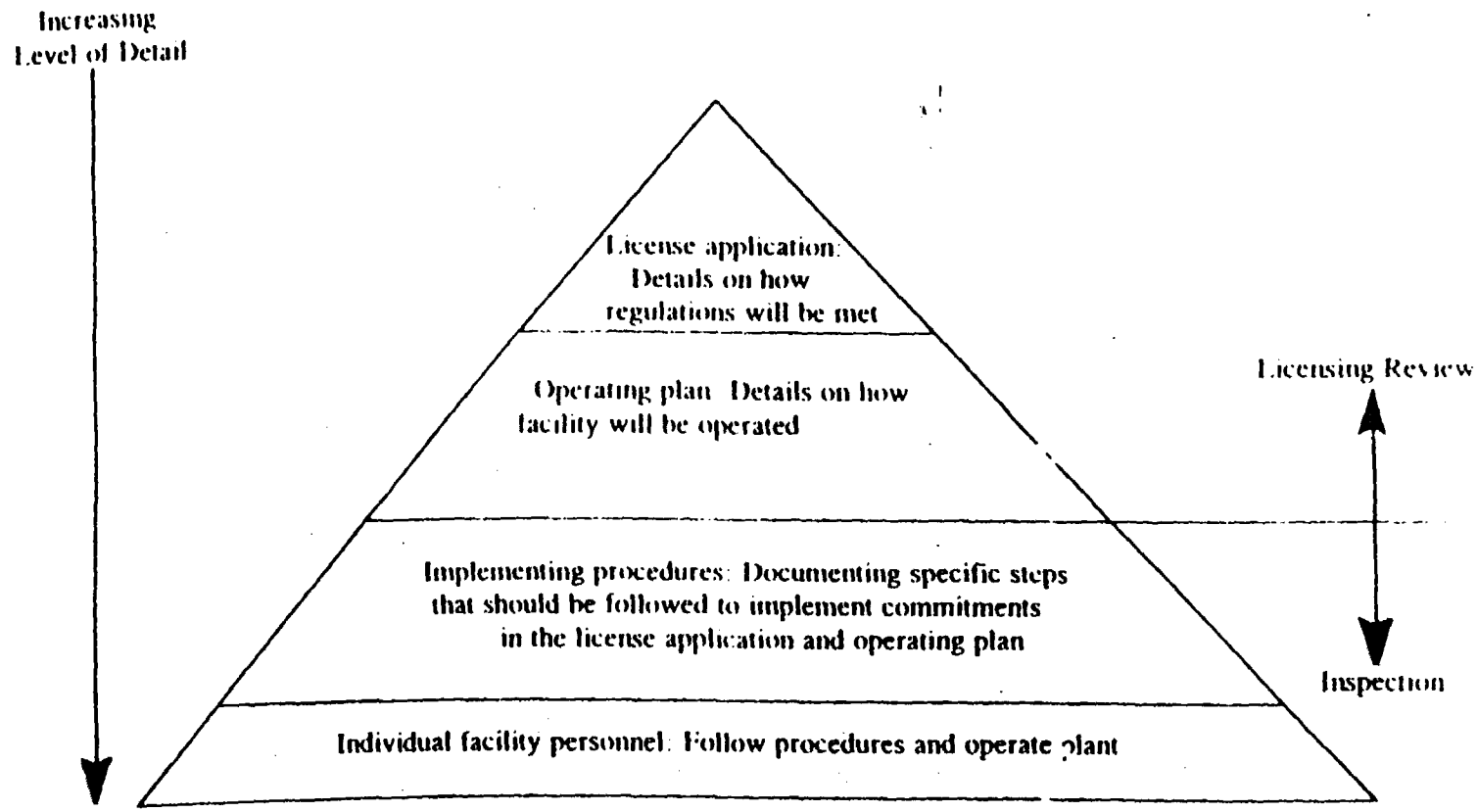

Figure 1 Outline of licensing versus inspection functions

applicant or licensee's proposal, NRC has no power to compel a licensee to come forward or to require a licensee to prepare a totally different proposal.

NRC's regulatory role in any licensing action is to apply the applicable regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved. The burden of proof is on the applicant or licensee to show that the proposed action is safe, and regulations are met, and to ensure continued compliance with the regulations.

In conducting its reviews, NRC is looking for regulatory truth (i.e., whether there is demonstration that an applicant's proposed approach meets the codified requirements), not scientific precision (i.e., having complete understanding and answers for all issues that could be raised concerning a proposal, including those not related to health and safety).

This basic regulatory philosophy is applied in both NRC safety and environmental reviews. For safety reviews, the NRC staff should examine whether applicant and licensee proposals are acceptable. Because of this, NRC staff should ensure that they do not look to drive licensees to the best possible solution. Basically, if a proposal meets the applicable regulations, the NRC staff has no basis for requiring something different. To do so would be imposing a requirement on a licensee. This is normally done through the issuance of an order with hearing rights according to 10 CFR Part 2, Subpart L.

In conducting environmental reviews, the staff needs to keep in mind that the NWPA requires the NRC to adopt DOE's EIS for the YM Repository to the extent practicable. The NRC will find it practicable to adopt the DOE EIS unless the action proposed to be taken by NRC differs in an environmentally significant way for the action described by DOE in the License application or significant and substantial new information or new considerations render DOE's EIS inadequate. The protocol for NRC staff review and adoption of the EIS has been described in the *Federal Register* (Draft Rule - May 5, 1988 53 FR 16131 and Final Rule - July 3, 1989 54 FR 27864).

In no instance, either with a safety or environmental review, should a reviewer determine that alternatives that are less protective than those proposed by the applicant are acceptable (in the case of a safety review) or preferred (in the case of an environmental review). NRC staff should always operate from a position that questions are asked when more information is needed to justify the proposal. However, the NRC staff should never tell licensees how they can do less or back off from what is proposed and still meet the regulations. To say it more succinctly; "Always ask them to do more to meet requirements, but never tell them to do less." If there is an issue associated with protection of public health and safety that requires prompt action from the licensee, NRC staff should prepare an immediately-effective order under 10 CFR 2.202(a)(5).

In pre-licensing meetings, for example, it is appropriate for staff to inform licensees when they are applying the regulations inappropriately.

Streamlining and Principles of Good Regulation

Streamlining of the licensing process is also consistent with the Commission's "Principles of Good Regulation." The following excerpts from these principles bear improving the efficiency of materials licensing reviews:

> "EFFICIENT. The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities . . . Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay."
>
> "CLEAR. . . . There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions [e.g., RAIs] should be readily understood and easily applied."
>
> "RELIABLE. . . . Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes."

The remaining sections of this guidance discuss the details of how the review should be conducted. They include a discussion on how staff should approach the review, what the format of the various products such as safety evaluation report and requests for additional information (RAIs) should look, and generic schedule for the licensing action. They are developed consistent with the regulatory framework discussed above.

3.0 Approach to Reviews

Several key elements or characteristics are considered necessary for effective streamlining of the licensing review process from both time-efficiency and regulatory-acceptability perspectives. These characteristics are:

- Empowered Reviewers

  Reviewers are given the freedom, within the agency's regulatory framework covering a licensing action, to control the conduct of the review, and to make licensing decisions without undue delay. Reviewers are able to exercise a high degree of independence to work toward timely resolution of technical issues. Complete licencing decisions in a period of time that meets the applicant's needs.

- Defined Goals

  Regulations define the goals for achieving safety. The Principles themselves are broad goals to be achieved that relate to safety, efficiency, and dependability of NRC's licensing actions. Regulations form the basis for all aspects of the licensing review, including RAIs, SERs, and environmental reviews. Licensing decisions are based on reasonable assurance of no undue risk to public health, safety and the environment.

- Control over RAIs

  Agency positions are to be readily understood by licensees, and should be consistent with written regulations. Preliminary Safety Evaluation Reports should be developed early in the review process to focus any needs for additional information and assure all technical areas of concern are adequately addressed by the applicant. Licensing will be constrained by the areas of review defined by the Yucca Mountain Review Plan. The goal of any licensing review is for no RAIs; however, if additional information is needed, the request(s) should be limited to one round of RAIs. The requests should be stated concisely, focused, and clearly convey what information is required.

- Defined Rules of Engagement

  Staff's review schedules and expectations of the applicant's response timeliness and quality will be defined and agreed upon by both parties. Applicants will be informed on how their application will be treated and the streamlined licensing program will be explained.

- Use of Licensing Review Teams

  When appropriate, multi disciplinary review teams are formed to conduct simultaneous reviews of various technical areas of an applicant's proposal.

- Discipline

  These procedures for streamlining provide discipline for an improved licensing process for the prompt resolution of technical issues. Reviewers should not enter into interrogatories on obviously unacceptable proposals. If issues cannot be resolved in a timely manner, the issue must be escalated to higher management levels within the NRC and the applicant's organization.

- Early Meetings

  Regulatory decisions are to be made without undue delay and to be promptly administered. Early meetings also contribute to understanding of NRC's positions, and help to clarify the information that is needed to resolve issues. Meet with applicants or licensees early in the review process to discuss preliminary findings and outstanding issues

Four primary milestones must be systematically completed in order to complete a regulatory and technical review of DOE's licensing action request in a time-efficient and regulatory-defensible manner. These milestones and their objectives are:

- Acceptance Reviews

  Determines the completeness of DOE's submitted materials, whether sufficient information is provided to support a detailed review, and the schedule of subsequent milestones

- Detailed Reviews

  Determines the safety and environmental acceptability of the proposed action, based on technical reviews of DOE's information and demonstrations of compliance with regulatory requirements

- Requests for Additional Information

  Documents insufficient or inadequate information submitted by DOE and communicates staff's requests for what additional information is needed to address the identified deficiencies

- Safety and Environmental Review Reports (SER)

  Communicates staff's position on the safety and environmental acceptability of DOE's request, which forms the basis of the subsequent licensing action

The acceptance review serves as the initial screening of DOE's application. DOE's application must provide sufficient information, both quality and quantity, by either inclusion or reference, to address the regulatory requirements of the proposed action. If the application does not meet this minimum standard, DOE should be informed of the deficiencies, and told that the NRC

does not consider the application complete enough to warrant a review. Accepting a sub-standard request for the detailed review places a timely and effective licensing review in jeopardy, because of the high potential for multiple RAIs while the applicant refines its analysis.

Completion of the other milestones is generally sequential, however, each milestone is not independent from the others. For example, the SER and EA should be initiated in a preliminary form during the early stages of the Detailed Review. The preliminary reports should follow the appropriate YMRP format, and be tied directly to a specific regulation. This allows the reviewer(s) to focus on regulatory-significant safety and environmental issues and reduces the potential likelihood of significant issues going unaddressed during subsequent milestones. Any deficiencies identified during the detailed review can be documented and highlighted in the preliminary report, along with what information would be required to address the deficiency.

These deficiencies documented in the preliminary reports constitute the foundation for the official RAIs, which will be communicated to DOE in writing. The goal of conducting the detailed review in this manner is to limit the RAIs to one round of staff request and applicant response.

Clear and early communication of potential problems or deficiencies is crucial for effective completion of the licensing review and is required by NWPA. Reviewers have been "empowered" to initiate early communication with applicant's by using teleconferences or videoconferences as a means of verifying the staff's understanding of the supplied information and determine which potential issues could be resolved by the applicant supplying additional information. The staff should also determine if the meeting should be conducted on site to better understand the nature of the application, if site conditions will be a factor in the final decision. Staff should remember that meetings with applicant's or licensee's are open to the public and must be noticed as such. A general procedure for the DWM has been developed outlining staff interactions with applicants (Attachment 1), however, some the processes describe may not be applicable due to some of the unique aspects of the HLW program.

Early communication with the applicant should also include discussions and agreement on a schedule for subsequent milestones in the review process. This discussion and agreement constitute the official "rules of engagement" for the remaining phases of the licensing action which must be communicated in writing at the completion of the acceptance review and the RAIs, if necessary. The consequences of not meeting the agreed schedule must be clearly communicated to the applicant in the RAI cover letter.

Empowerment also requires that reviewers work with a high degree of independence such that unresolved issues are communicated to the appropriate licensee management level to assure timely resolutions. If reviewers work within the regulatory framework outlined in Section 2 of this guidance, they should be able to independently conduct a review with little management involvement that complies with programmatic needs and regulatory requirements.

If reviewers find that timely resolution is not being achieved even after contact with licensee management, the reviewers should raise a concern to NRC management. This helps ensure that NRC management is responsive to the issues, and is focused on getting reviews done in a timely manner.

All official requests for information, schedule agreements, and the applicant's responses must be communicated in writing in order to eliminate potential misunderstandings from verbal discussions, provide an official record of staff/applicant interactions, and document the applicant's commitments for inclusion in the licensing documents. As a goal, written communications should be in a style and level of technical detail such that an informed member of the general public could understand the document. A good "rule-of-thumb" to gage whether a document is targeted to an informed member of the public is to ask, "Could this document be read and understood by a high school graduated who has taken chemistry, mathematics and physics?" Issuing documents that are difficult to read and understand do not promote effective and timely licensing reviews. It is not necessary to send all outgoing correspondences to the technical editor, however, the SER should be sent to a technical editor before being released to the public.

4.0 Format and Content of Documents

Correspondence and documents from each of the licensing review milestones should be logically organized and contain adequate information to convey NRC's position and requirements in a simple, clear and concise manner.

The acceptance review does not determine the technical adequacy of the submitted information, unless the Commission decides to determine the acceptability of an application on its technical adequacy, as well as completeness (for example, commercial waste disposal facilities).

The applicant must be notified in writing of the acceptance review determination, within 30 days of receipt of the request. The acceptance review is documented by a brief, one to two page letter recommending acceptance for initiating the detailed review or rejection. Upon acceptance, the letter also sets a schedule of the pending detailed review, including intermediate milestones and the anticipated completion date. The letter should include a disclaimer stating that the additional information requests may result from the detailed review and the projected review schedule is contingent upon the applicant supplying high-quality, timely responses to any information requests. The letter must also inform the applicant that failure to respond to additional information requests within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). The only exception to the written notification is when the detailed review of a request can be completed and the licensing action taken within 30 days.

Written RAIs should be focused, brief and clear. An RAI should include three parts:

- Issue

  A summary of the identified deficiency and the regulatory requirement

- Discussion

  A summary of the applicant's information or response and why it is unsatisfactory

- Action Needed

  A concise statement of what information is needed to address the deficiency

RAIs should be numbered sequentially with the numbering for an individual RAI remaining constant through the course of the licensing review. The cover letter transmitting the RAIs must include a schedule for the applicant to provide responses and the dates of the remaining milestones. The letter must also reiterate the statement from the acceptance review that failure to respond within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). Additional guidance for the style and format of RAIs is provided in Attachment 2.

The content of the SER shall be based on the guidance provided in the YMRP. The technical basis for the staff evaluations and conclusions is focused first on the safety and environmental

issues, and then on the regulatory issues. If there are limits and restrictions imposed as a condition of approval and agreed to by the applicant, they need to be addressed as requirements in the license. The technical reviewer should notify the licensing project manager as soon as practical if this is the case.

The format for the SER should customarily follow the outline of the YMRP. The findings that have been made, as a result of the detailed review, will be stated in the SER at the conclusion of each section. If there are limiting conditions that need to be imposed, they should be highlighted for inclusion in the license. In all cases, the limiting conditions that are enumerated in the license shall be identified in the SER.

5.0 Yucca Mountain Licensing Schedule

The general timing of the HLW licensing action is defined in Section 114(d) of the NWPA as amended, which specifies that the Commission shall issue a final decision regarding issuance of a construction authorization within 3 years of DOE's application with a provision for a 1-year extension. The specific schedule for the licensing action will be developed upon receipt of License Application from DOE. The DOE published it's Congressionally mandated Viability Assessment on December 18, 1998 which identified the following major repository milestones which are intended to be goals for completing licensing actions:

DOE Publish Notice of Availability for the DEIS.....7/30/99
DOE Publish Notice of Availability for the FEIS.....8/25/00
DOE Notifies State of Site Recommendation Decision..... 4/13/01
DOE Issues Site Recommendation to President..... 7/27/01
DOE Submit LA to NRC..... 3/1/02
NRC Decision to Authorize Construction.....2005
DOE Update LA to Receive and Possess Nuclear Waste..... 2008
If Licensed, First Possible Waste Emplacement at Repository..... 2010
Start Permanent Closure?.....2110

Staff Interactions with Applicants

Introduction

The Office of Nuclear Material Safety and Safeguards (NMSS), Division of Waste Management, has instituted several project management measures to ensure prompt review of licensing action requests. This DWM internal procedure has been developed to further clarify the current process for DWM staff interactions with the applicant (new application, amendment, or renewal).

Prioritization

- Work in DWM is prioritized based on (1) safety issues of operating facilities and facilities in decommissioning and reclamation (2) new applications and license renewals (3) routine license amendments that allow flexibility in licensed activities, and (4) other work.

- It is the responsibility of the appropriate Section Chief or Team Leader, in consultation with the Branch and Division management, to prioritize work in accordance with this internal procedure. The Section Chief or Team Leader will assign a specific review team for each application.

Application

- The Project Manager (PM) is the primary point-of-contact for all licensing-related communications with the applicant. In the event the assigned PM is not available, a backup PM may be substituted on a case-by-case basis.

- The PM will arrange and chair pre-application meetings with the applicant.

  For commercial applications, the PM, in conjunction with the appropriate Licensing Assistant (LA), will ensure that a docket number is assigned and a TAC number is opened as fee billable during the pre-application phase. The potential applicant should be informed of this, prior to the first pre-application meeting.

  During a pre-application meeting, the PM should inform the applicant that the applicant should provide a written statement as to whether the appropriate standard review plan (SRP) was followed in developing its application and safety analysis report. This statement should also include a description of any deviations from the SRPs taken by the applicant. Additionally, the PM should inform the applicant of the elements of this procedure during the pre-application meeting.

- The PM will ensure the expedited processing of incoming licensing actions by following NMSS Policy and Procedures Letter 1-51, "Policy and Criteria for Initial Processing of Incoming Licensing Actions."

  This policy requires a general acceptance review within 30 days of receipt of an application. While primarily an administrative review, the general acceptance review includes, but is not limited to, the following (1) legibility of drawings, (2) general

adequacy of information, (3) proprietary information, and (4) obvious technical inadequacies. The objective of the acceptance review is to verify that the application contains sufficient information before staff begins an in-depth technical review using the SRPs.

- The assigned technical reviewers shall follow the applicable SRP(s). The PM will monitor the project to ensure that the SRP(s) are being followed by the assigned technical reviewers.

  The SRPs provide guidance to DWM staff reviewers and indirectly provide guidance to applicants on the content of their applications. The SRP objectives are to (1) summarize the technical positions acceptable for meeting the regulatory requirements for application approval; (2) describe the procedures by which the DWM staff determines that these requirements have been satisfied; and (3) documents the practices developed by the staff in previous reviews of applications. The SRPs assist in ensuring the quality and consistency of staff reviews and in establishing well-defined bases from which to evaluate proposed changes in the scope of the reviews. Deviations from following the SRPs may be done on a case-by-case basis, provided approval by the appropriate Branch Chief is obtained and the review is documented.

- The PM is responsible for written communications with the applicant.

  The PM, in conjunction with the associated technical reviewers and the LA, will prepare all written correspondence with the applicant, including, but not limited to, general correspondence, requests for additional information, safety evaluation reports, and licenses.

- The PM, in conjunction with the appropriate LA, will ensure all correspondence is docketed.

  Receipt of correspondence from a current or potential applicant, including facsimiles, by any DWM staff member will be provided to the appropriate PM/LA for docketing.

Requests for Additional Information

The PM and all associated technical reviewers should be aware of the following:

- NMSS/DWM management has indicated very strongly to the industry that improved performance on their part, in relation to the quality of submittals, is required. DWM staff members should reiterate this message as often as is warranted.

- With Branch Chief approval, in consultation with DWM management, partial or incomplete applications or RAI responses will not be reviewed. The applicant will be advised by telephone, and subsequently in writing, of the basis for this determination.

- If the staff's review requires additional applicant information, RAIs will be issued in a stand format in accordance with Branch guidelines.

This RAI includes a description of the information needed, the regulatory basis, and the technical and safety basis. The objective of using and RAI standard format is to ensure that each RAI item is unambiguous and focused on a regulatory or safety issue.

- Each significant RAI should be discussed in a meeting open to the public and chaired by the PM to assure that the applicant understands the staff's expectations regarding the RAI.

- The NRC's goal is to see improvement in new applications and amendments such that no RAI has to be issued. One round of RAIs and applicant responses (perhaps two) will be considered acceptable, but staff will (1) expect a prompt (<90 day) response from the applicant and (2) slip the review schedule accordingly if beyond 90 days.

  The applicant will be notified of this expectation/warning in the RAI cover letter. The applicant will also be advised that the extent of the slip in the staff's resumption of the review may exceed the slip in the applicant' response time.

- When more than two rounds of RAIs and responses are needed, with DWM Director approval, the staff will (1) identify its positions and concerns, and (2) suspend further technical review pending certification of application sufficiency by the applicant and its respective Owner's Group or other independent third party. The applicant will be notified of this action in writing as soon as possible.

Style and Format for Requests for Additional Information

The DWM staff reviews and evaluates the analysis and design of uranium recovery, decommissioning, and high-level waste facilities to determine technical adequacy and compliance with regulatory requirements. Requests for additional information (RAI) to any license or application should follow the following style and format as outlined below in order to ensure proper communications as outlined in NRC policy requirements.

RAIs related to the technical adequacy of the document under review should state all relevant problems and issues to be resolved prior to approval in a manner that is clear, concise, and consistent with the regulations and good engineering practice. This is considered primarily an exchange of technical information through which the staff elicits the information necessary for it to determine if the applicant has demonstrated compliance with the regulations. The staff may provide further supporting information depending upon the complexity of the request.

During the technical review, some RAIs may be related to an apparent failure to meet regulatory requirements, which must be satisfied prior to reaching a licensing decision. In this case, the RAI should identify the specific section of the regulations, and other supporting documents (Regulatory Guides, SRP, NUREGs, ASME/ASTM codes) that relate to good engineering in support of meeting the regulations. In this type of item, it is expected that supporting information will be provided, as necessary, both from a technical perspective and a regulatory one.

For major licensing actions, such as new applications or renewals, RAIs will be delineated by chapter and section, preferably following the organization of the SRP. A general regulatory applicability statement (example given below) will be provided for each topical area. The general applicability statement will apply to all items in that area and will reference the regulatory requirements applicable to that topic. Each request will have an action verb and an object which will clearly and concisely identify the information requested. Further technical information will be provided in a separate paragraph for that item, if necessary. If an item requires further regulatory citations, it will be provided in the additional information paragraph.

Examples of action verbs that elicit knowledge, comprehension, application, analysis, synthesis, and skills are:

analyze	assess	attach	choose
clarify	classify	combine	compare
conclude	contrast	construct	defend
define	demonstrate	determine	describe
differentiate	discuss	distinguish	establish
evaluate	explain	find	identify
illustrate	indicate	justify	label
list	measure	name	perform
plan	position	provide	rate
reproduce	resolve	revise	select
specify	summarize	support	show
state	turn	translate	use

Example General Applicability Statement

This document, titled Request for Additional Information (RAI), contains a compilation of additional information requirements, identified to-date by the U.S. Nuclear Regulatory Commission staff, during its review of the applicant's application and Safety and Environmental Report. NUREG [_____] Standard Review Plan for [_____] was used to review the application. This RAI follows the same format as NUREG [_____].

Each individual RAI describes information needed by the staff for it to complete its review of the application and to determine whether the applicant has demonstrated compliance with the regulatory requirements. Where and individual RAI relates to the applicant's apparent failure to meet one or more regulatory requirements, or where an RAI specifically focuses on compliance issues associated with one or more specific regulatory requirements (e.g., specific design criteria or accident conditions), such requirements will be specified in the individual RAI.

GUIDANCE DOCUMENT

FOR

STREAMLINING THE

DECOMMISSIONING PROGRAM

FOR FUEL CYCLE AND MATERIALS LICENSEES

DIVISION OF WASTE MANAGEMENT

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

January 8, 1999

1.0 INTRODUCTION TO STREAMLINED DECOMMISSIONING LICENSING

NRC's regulations in Title 10 of the Code of Federal Regulations set forth the technical and financial criteria for decommissioning licensed nuclear facilities. These regulations are designed to ensure that licensees operate and decommission their facilities in a safe and timely manner, and that they set aside adequate funds to ensure that the decommissioning can be accomplished in the event the licensee is unable to complete the activities. NRC's responsibility is to ensure that these regulations are met by licensees. The decommissioning program typically consists of amendments to licenses that authorize operational and decommissioning activities, and the termination of a license once residual radioactivity is cleaned up to levels that meet NRC's regulations. In addition to the public health and safety reviews associated with licensing actions, the NRC licensing program must address National Environmental Policy Act (NEPA) responsibilities that are set forth in 10 CFR Part 51.

The purpose of this document is to provide staff in the decommissioning program with guidance for conducting streamlined licensing reviews. A streamlined review, in addition to accomplishing the necessary health and safety review objectives, also completes a licensing decision in a period of time that meets the licensee's needs. A streamlined review process imposes discipline, encourages communication (both formal and informal) between NRC and the licensee, and establishes schedules for all parties. This process is intended to facilitate staff reviews and licensing decisions in accordance with defined and agreed upon schedules. This guidance supplements existing guidance principally contained in the "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees," (NUREG/BR-0241) that contains both procedural and technical guidance for conducting decommissioning reviews.

This guidance is applicable to all forms of decommissioning licensing actions such as renewals, amendments, and license terminations. It also applies to non-licensees, such as responsible parties for SDMP sites, that are remediating contaminated sites and facilities. This procedure does not apply to the inspection or enforcement programs. This procedure does not at this time address other related "streamlining" initiatives that are being investigated, such as the Commission-directed materials decommissioning pilot program, or the Standard Review Plan that is being developed for license termination reviews.

A review of any licensing action is not intended to be an exhaustive evaluation of all aspects of decommissioning a facility. Specific information about implementation of the program outlined in an application and/or a decommissioning plan is obtained through the NRC review of procedures and operations done as part of the inspection function. The detailed steps of a licensing review are discussed later in this guidance, along with a generic schedule for nearly all expected decommissioning licensing actions.

2.0 REGULATORY PHILOSOPHY

Streamlining and NRC's Safety Philosophy

Since the Atomic Energy Act of 1954 was passed, the Commission has been engaged in a continuing process of interpreting and applying the agency's basic responsibilities as defined by that law: viz., to "protect public health and safety," "assure the common defense and security," "minimize danger to life or property," and "provide adequate protection." These terms are not defined in the AEA, nor are they self-explanatory. The basic NRC Safety Philosophy is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

> "LICENSEE RESPONSIBILITY embodies the principle that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing, and other activities on those areas where the need, and the likely safety and safeguards benefit, are greatest."

To state it more succinctly, the safe operation of any nuclear facility is the responsibility of the licensee. This philosophy is an important foundation for how NRC staff is to conduct their reviews in general, and streamlined licensing reviews in particular. Streamlining begins with a recognition of NRC's regulatory role in relation to its licensees, i.e., that licensees have the primary responsibility for ensuring the safety of nuclear facilities.

Implementing this philosophy, means the following:

- NRC does not select sites or designs or participate with licensees or licensees in selecting proposed sites or designs.

- NRC's role is not to monitor all licensee activities but to audit them. NRC should evaluate whether the proposal meets the applicable regulations based on a review of what is in the application. Staff audit calculations should be used in very limited situations such as unique proposals involving new methods or assumptions. Otherwise, the NRC staff should review the application to ensure that assumptions are justified, methods used are acceptable and applicable over the range presented in the application, the model was properly applied, and the results are acceptable. Staff can and should do quick, back-of-the-envelope calculations; however, in-depth, detailed performance assessments can be limited to a very few applications. Figure 1 shows the relationship between licensing reviews and inspections, and the level of detail that is examined in each.

- The three outcomes available to NRC at the conclusion of a licensing review are: (1) grant the application; (2) grant the application subject to certain conditions

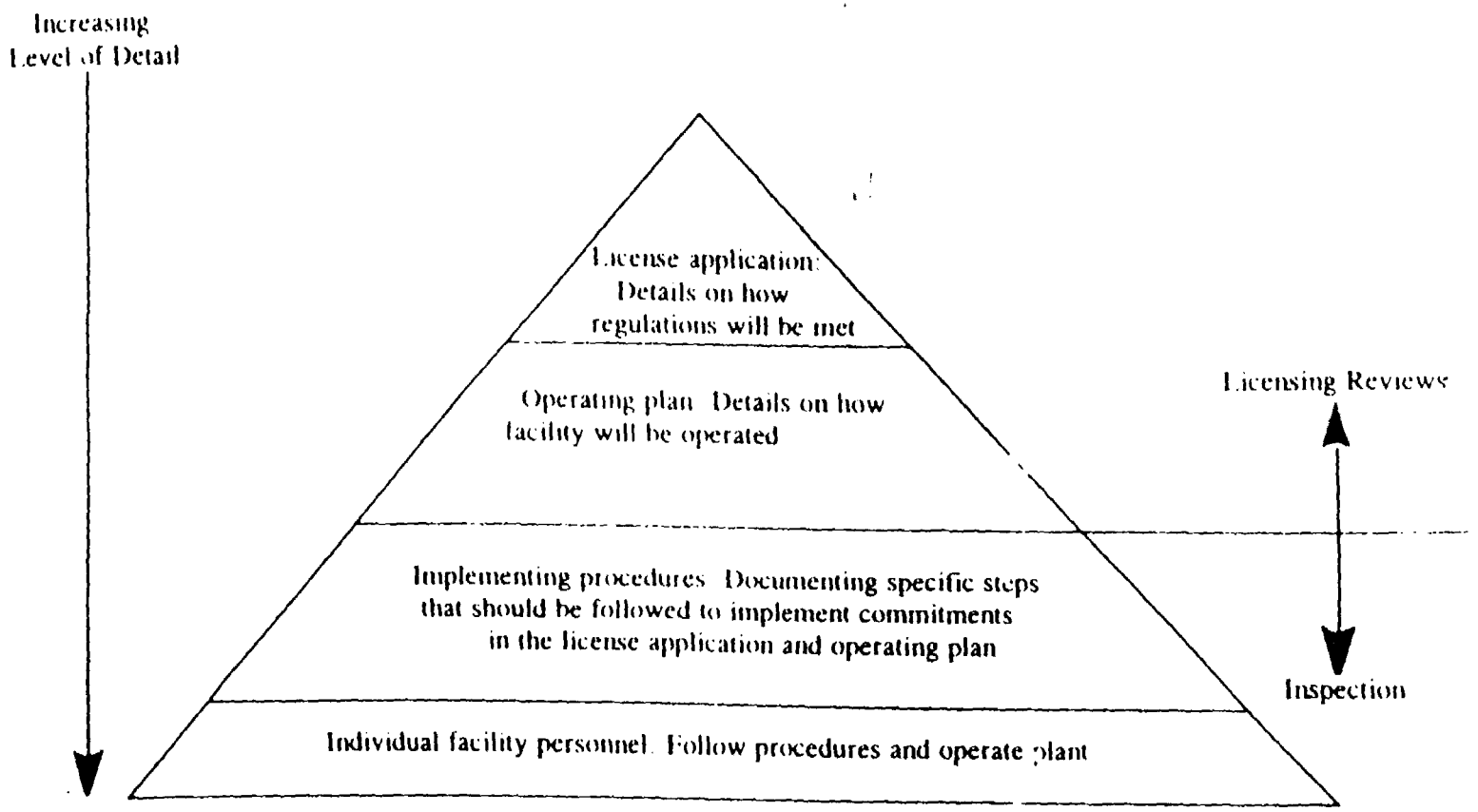

Figure 1 Outline of Licensing versus Inspection Functions

agreed upon by the licensee; or (3) deny the application. NRC has no power to compel a licensee to prepare a totally different proposal.

NRC's regulatory role in any licensing action is to apply appropriate regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved. The burden of proof is on the licensee to show that the proposed action is safe, and regulations are met, and to ensure continued compliance with the regulations.

In conducting its reviews, NRC is looking for regulatory truth (i.e., whether there is demonstration that the licensee's proposed approach meets the codified requirements), not scientific precision (i.e., having complete understanding and answers for all issues that could be raised concerning a proposal, including those not related to health and safety).

This basic regulatory philosophy is applied in both NRC safety and environmental reviews. For safety reviews, the NRC staff should examine whether licensee proposals are acceptable. Because of this, NRC staff should ensure that they do not look to drive licensees to the best possible solution. Basically, if a proposal meets the applicable regulations, the NRC staff has no safety basis for requiring something different. To do so would be imposing a requirement on a licensee. This is normally done through the issuance of an order with hearing rights according to 10 CFR Part 2, Subpart L.

In conducting environmental reviews, the National Environmental Policy Act of 1969 requires an evaluation of the environmental impacts. However, unlike the safety review discussed earlier, there are no specific requirements that determine NEPA environmental compliance. Consistent with 10 CFR 51.21, all licensing actions require an environmental assessment unless the NRC is completing either an Environmental Impact Statement, or the staff has found that the action is categorically excluded according to one of the criteria found in 10 CFR 51.22. For decommissioning activities, amendment applications may meet one of the four exemptions in 10 CFR 51.22(c)(11), and thus be categorically excluded.

For evaluations of environmental impacts, the staff should focus its evaluation efforts on the proposed licensing action. The Commission position in the Statement of Consideration for Part 51 is that the alternative analysis performed in support of any environmental impact analysis should be completed by using "reconnaissance-level" information. This type of information is generally available and does not require any or much site-specific work, such as site characterization, to obtain. The Commission's and Council on Environmental Quality's reason for using reconnaissance-level information is that although it may be possible to optimize designs or provide more detailed impact analysis, it is highly unlikely that a detailed examination of the alternatives would reveal any significant environmental impacts that would escape a review done with reconnaissance-level information.

This is an important point because the NRC staff can only deny an application for one of two environmental reasons. First, the environmental impacts are found unacceptable (i.e., do not comply with applicable State or Federal laws or regulations, such as the Clean Air Act), or second, one of the alternatives analyzed proves to be obviously superior. The determination of obvious superiority includes both enhanced environmental benefit at only minimal cost increases. In no instance either with a safety or environmental review, should a reviewer

determine that alternatives that are less protective than those proposed by the applicant are acceptable (in the case of the safety review) or preferred (in the case of the environmental review). NRC staff should always operate from a position that questions are asked when more information is needed to justify the proposal. If there is an issue associated with protection of public health and safety that requires prompt action from the licensee, NRC staff should prepare an immediately-effective order under 10 CFR 2.202(a)(5).

In pre-licensing meetings, for example, it is appropriate for staff to inform licensees when they are applying the regulations inappropriately and unnecessarily (submitting an environmental report, for example, when a categorical exclusion is acceptable).

Streamlining and Principles of Good Regulation

Streamlining of the materials licensing process is also consistent with the Commission's "Principles of Good Regulation." The following excerpts from these principles bear on improving the efficiency of materials licensing reviews:

> "EFFICIENT. The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities . . . Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay."
>
> "CLEAR. . . . There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions [e.g., RAIs] should be readily understood and easily applied."
>
> "RELIABLE. . . Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes."

The remaining sections of this guidance discuss the details of how streamlined reviews should be conducted. They include a discussion on how staff should approach reviews, what the format of the various products such as safety evaluation reports, environmental assessments, and requests for additional information (RAIs) should look like, and generic schedules for various types of licensing actions. They are developed consistent with the regulatory framework discussed above.

3.0 APPROACH TO STREAMLINING LICENSING REVIEWS

Several key elements or characteristics are considered necessary for effective streamlining of the licensing review process from both time-efficiency and regulatory-acceptability perspectives. These characteristics are:

- Empowered Reviewers

  Reviewers are given the freedom, within the agency's regulatory framework covering a licensing action, to control the conduct of the review, and to make licensing decisions without undue delay. Reviewers are able to exercise a high degree of independence to work toward timely resolution of technical issues and complete licensing decisions in a period of time that meets the licensee's needs.

- Defined Goals

  Regulations define the goals for achieving safety. The Principles of Good Regulation themselves are broad goals to be achieved that relate to safety, efficiency, and dependability of NRC's licensing actions. Regulations form the basis for all aspects of the licensing review, including RAIs, SERs, and environmental reviews. Licensing decisions are based on reasonable assurance of no undue risk to public health, safety and the environment. Licensees have a reasonable expectation of timeliness.

- Control over RAIs

  Agency positions are to be readily understood by licensees, and should be consistent with written regulations. Preliminary Safety Evaluation Reports should be developed early in the review process to focus any needs for additional information and assure all technical areas of concern are adequately addressed by the licensee. Licensing will be constrained by the areas of review defined by the Standard Review Plans. The goal of any licensing review is for no RAIs; however, if additional information is needed, the request(s) should be limited to one round of RAIs. The requests should be stated concisely, be focused, and clearly convey what information is required.

- Defined Rules of Engagement

  Staff's review schedules and expectations for timeliness and quality in the licensee's response will be defined and agreed upon by both parties. Licensees will be informed on how their application will be treated and the new (streamlined) licensing program will be explained.

- Assessment of Complexity and Applicability of Existing Precedents, Policy, Regulations and Guidance .

  Staff will examine each licensing proposed action and plan for only the necessary and sufficient procedures to act on it. For complex cases or cases with unusual public, State, or Congressional interest, it may be appropriate to conduct public meetings to discuss the staff's plans and decisions, for example. Simpler cases can follow a more streamlined process, consistent with the minimum required by law and regulation.

- Use of Licensing Review Teams

  When appropriate, multi disciplinary review teams are formed to conduct simultaneous reviews of various technical areas of an licensee's proposal.

- Discipline

  These procedures for streamlining provide discipline for an improved licensing process for the prompt resolution of technical issues. Reviewers should not enter into interrogatories on obviously unacceptable proposals. If issues cannot be resolved in a timely manner, the issue must be escalated to higher management levels within the NRC and the licensee's organization.

- Early Meetings

  Regulatory decisions are to be made without undue delay and to be promptly administered. Early meetings also contribute to understanding of NRC's positions, and help to clarify the information that is needed to resolve issues. Staff should meet with licensees early in the review process to discuss preliminary findings and outstanding issues

Four primary milestones must be systematically completed in order to finish a review of an licensee's licensing action request in a time-efficient and regulatory-defensible manner. These milestones and their objectives listed below, should be conducted in accordance with the characteristics of the streamlined licensing approach:

- Acceptance Reviews

  Determines the completeness of the licensee's submitted materials, whether sufficient information is provided to support a detailed review, and the schedule of subsequent milestones

- Detailed Reviews

  Determines the safety and environmental acceptability of the proposed action, based on technical reviews of the licensee's information and demonstrations of compliance with regulatory requirements

- Requests for Additional Information

  Documents insufficient or inadequate information submitted by the licensee and communicates staff's requests for what additional information is needed to address the identified deficiencies

- Safety and Environmental Review Reports (SER, EA, or EIS)

  Communicates staff's position on the safety and environmental acceptability of the licensee's request, which forms the basis of the subsequent licensing action

The acceptance review serves as the initial screening of an licensee's request and provides the initial estimate for allocating staff resources to support a complete licensing review. An licensee's request must provide sufficient information, both quality and quantity, by either inclusion or reference, to address the regulatory requirements of the proposed action. Acceptance reviews should be performed on all incoming requests for license amendments, license renewals, and new license applications in the decommissioning program. For applications that do not meet this minimum standard, the licensee should be informed of the deficiencies, and told that the NRC does not consider the application complete enough to warrant a review. Accepting a substandard request for the detailed review places a timely and an effective licensing review in jeopardy, because of the high potential for multiple RAIs while the licensee refines its analysis.

Completing the other milestones is generally sequential, however, each milestone is not independent from the others. For example, the SER and EA reports should be initiated in a preliminary form during the early stages of the Detailed Review. The preliminary reports should follow an appropriate format, and be tied directly to a specific regulation. This allows the reviewer(s) to focus on regulatory-significant safety and environmental issues and reduces the potential likelihood of significant issues going unaddressed during subsequent milestones. Any deficiencies identified during the detailed review can be documented and highlighted in the preliminary report, along with what information would be required to address the deficiency.

These deficiencies documented in the preliminary reports constitute the foundation for the official Requests for Additional Information (RAIs), which will be communicated to the licensee in writing. The goal of conducting the detailed review in this manner is to limit the RAIs to one round of staff request and licensee response.

Clear and early communication of potential problems or deficiencies is crucial for effective completion of the licensing review. Reviewers are "empowered" to initiate early communication with licensees' by using teleconferences or videoconferences as a means of verifying the staff's understanding of the supplied information and determine which potential issues could be resolved by the licensee supplying additional information. Under the provisions of 10 CFR 2.101, these communications can occur even before an application is submitted. The staff should also determine if the meeting should be conducted at the site to better understand the nature of the application, if site conditions will be a factor in the final decision. Staff should remember that meetings with applicant's or licensee's are open to the public and must be

noticed as such. Procedures outlining staff interactions with licensees are provided in Attachment 1.

Early communication with the licensee should also include discussions and agreement on a schedule for subsequent milestones in the review process. This discussion and agreement constitute the official "rules of engagement" for the remaining phases of the licensing action which must be communicated in writing at the completion of the acceptance review and the RAIs, if necessary. The consequences of not meeting the agreed schedule must be clearly communicated to the licensee in the RAI cover letter.

If the licensee does not respond in that time period, or provides answers that are incomplete to finish the review, the application should be considered for denial under the provisions of 10 CFR 2.108. If such a denial is issued, then the licensee should be informed of the hearing rights available to it under the provisions of 10 CFR Part 2, Subpart L. In any event, the licensee's failure to respond within the specified time frame will at least result in the proposed action losing its place in the review "queue."

Empowerment also requires that reviewers work with a high degree of independence such that unresolved issues are communicated to the appropriate licensee management level to assure timely resolutions. If reviewers work within the regulatory framework outlined in Section 2 of this guidance, they should be able to independently conduct a review with little management involvement that complies with programmatic needs and regulatory requirements.

If reviewers find that timely resolution is not being achieved even after contact with licensee management, the reviewers should raise a concern to NRC management. This helps ensure that NRC management is responsive to the issues, and is focused on getting reviews done in a timely manner.

All official requests for information, schedule agreements, and the licensee's responses must be communicated in writing in order to eliminate potential misunderstandings from verbal discussions, provide an official record of staff/licensee interactions, and document the licensee's commitments for inclusion in the licensing documents. As a goal, written communications should be in a style and level of technical detail such that an informed member of the general public could understand the document. A good "rule-of-thumb" to gage whether a document is targeted to an informed member of the public is to ask, "Could this document be read and understood by a high school graduate who has taken chemistry, mathematics and physics?" Issuing documents that are difficult to read and understand do not promote effective and timely licensing reviews.

4.0 FORMAT AND CONTENT OF DOCUMENTS

Correspondence and documents from each of the licensing review milestones should be logically organized and contain adequate information to convey NRC's position and requirements in a simple, clear and concise manner.

The acceptance review does not determine the technical adequacy of the submitted information, unless the Commission decides to determine the acceptability of an application on its technical adequacy, as well as completeness (for example, commercial waste disposal facilities).

The licensee must be notified in writing of the acceptance review determination, within 30 days of receipt of the request. The acceptance review is documented by a brief, one to two page letter recommending acceptance for initiating the detailed review or rejection. Upon acceptance, the letter also sets a schedule of the pending detailed review, including intermediate milestones and the anticipated completion date. The letter should include a disclaimer stating that the additional information requests may result from the detailed review and the projected review schedule is contingent upon the licensee supplying high-quality, timely responses to any information requests. The letter must also inform the licensee that failure to respond to additional information requests within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). For complex cases or cases with unusual State, Congressional, or public interest, the letter should note the uncertainties associated with addressing these areas. The only exception to the written notification is if the detailed review of a request can be completed and the licensing action taken within 30 days.

Written requests for additional information should be focused, brief and clear. An RAI should include three parts:

- Issue

  A summary of the identified deficiency and the regulatory requirement

- Discussion

  A summary of the licensee's information or response and why it is unsatisfactory

- Action Needed

  A concise statement of what information is needed to address the deficiency

RAIs should be numbered sequentially with the numbering for an individual RAI remaining constant through the course of the licensing review. The cover letter transmitting the RAIs must include a schedule for the licensee to provide responses and the dates of the remaining milestones. The letter must also reiterate the statement from the acceptance review that failure to respond within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). Additional guidance for the style and format of RAIs is provided in Attachment 2.

The content of the SER and EA shall be based on the guidance provided in the NMSS Decommissioning Handbook, Appendices M (for an amendment to authorize decommissioning) and L. The technical basis for the staff evaluations and conclusions is focused first on the safety and environmental issues, and then on the regulatory issues. If there are limits and restrictions imposed as a condition of approval and agreed to by the licensee, they need to be addressed as requirements in the license. The technical reviewer should notify the licensing project manager as soon as practical if this is the case.

If the SER and EA are generated for amendments to licenses, the reviewer should limit the scope of the review to the topics necessary for the amendment application and make the necessary limited findings, as appropriate. The review should focus on the regulatory requirements, and determine compliance with these regulations. The safety and environmental reviews can be conducted in parallel rather than series. In some circumstances, it may be possible to complete the environmental review earlier than the safety review. When this is the case, the reviewer should complete the environmental review, and publish the results in the Federal Register.

Keep in mind that the environmental review should include any consultation with the Fish and Wildlife Service under the Endangered Species Act and the State Historic Preservation Officer under the Historic Preservation Act, and the appropriate state agency administering environmental compliance. These consultations can also be initiated in parallel during the environmental review rather than waiting for completion of the EA or EIS.

SECY-94-270 dated November 2, 1994 describes the agency policy for documenting the results of consultation with other agencies or persons on environmental assessments. Only a brief statement of the consulted agency or person's comments and the agency's response is necessary in the EA. The EA should identify the agency or person consulted, note the date of the consultation, summarize the consultation, and provide the resolution of any comments received. If the consulted agency or person made no specific comments, a simple statement to that effect, such as "no comment," "no objection," or "agreement" would be sufficient. However, if the agency or person made specific comments, these should be summarized along with the agency's response.

The format for the SER and the EA (or EIS) should customarily follow the outline in the Decommissioning Handbook for major actions, and the examples given in the attached appendix for smaller more routine actions. The findings that have been made, as a result of the detailed review, will be stated in the SER or EA at the conclusion of each section. If there are limiting conditions that need to be imposed, they should be highlighted for inclusion in the license. In all cases, the limiting conditions that are enumerated in the license shall be identified in the SER or EA.

5.0 GENERIC LICENSING SCHEDULES

The schedules laid out below are intended to be goals for completing licensing actions. They are not intended are rigid milestones that must be met. Individual circumstances may dictate a different schedule depending on the particular circumstances like availability of staff.

Generic Licensing Schedule		
Licensing Action	**Duration**	**Cumulative**
Simple Amendments (routine surety updates at non-operational facilities, no deficiencies)	30 days	30 days
Standard Amendments and License Terminations (surety updates at operational facilities, Type I and II decommissioning actions, including license terminations, no deficiencies)	60 days	60 days
Major Amendments (approval of a decommissioning plan for Type III or IV decommissioning)		
Safety Review		
Acceptance Review	30 days	30 days
Early SER and Requests for Additional Information (RAIs)	30 days	60 days
Licensee Response	60 days	120 days
Complete Technical Review (final SER)	30 days	150 days
Complete Licensing Action	30 days	180 days
Environmental Assessment (For Type IV decommissioning only. Type III's have a categorical exclusion)		
Consult with U.S. Fish and Wildlife Service (FWS)[1]	60 days	60 days
Consult with State Historic Preservation Officer (SHPO)	60 days	60 days

[1]Undertake consultation as needed. Otherwise get letter from Service that no impact will occur to endangered species.

Generic Licensing Schedule			
Licensing Action		**Duration**	**Cumulative**
	Complete Environmental Assessment[2]	60 days	60 days
	Consult with State Environmental Officer (SEO)	15 days	75 days
	Issue Finding of No Significant Impact[3]	30 days	105 days
Major Application with Environmental Impact Statement (Decommissioning plan for restricted release SDMP site, e.g.)			
	Safety Review (note–EIS development is usually on critical path, not safety review)		
	Acceptance Review	30 days	30 days
	Early SER and RAI	120 days	150 days
	Licensee response	60 days	210 days
	Complete Technical Review (final SER)	90 days	300 days
	Complete Licensing Action	45 days	345 days
	Environmental Review		
	Consult with FWS	60 days	60 days
	Consult with SHPO	60 days	60 days
	Consult with SEO	60 days	60 days
	Complete Draft Environmental Impact Statement (EIS)	240 days	300 days
	Issue for public comment, evaluate public comments	120 days	420 days
	Compete Final EIS	60 days	480 days

[2]Do not complete this step if action is categorically excluded or requires and Environmental Impact Statement.

[3]Complete only if previous step completed.

Generic Licensing Schedule			
Licensing Action		**Duration**	**Cumulative**
License Termination for Type III or IV Decommissioning (after approval of Decommissioning Plan)--Final Status Survey Report Review, confirmatory survey (if performed), and termination of license			
	Perform Acceptance Review of FSSR	30 days	30 days
	Notify Licensee of Deficiencies, if any	45 days	75 days
	Resolution of deficiencies by licensee in FSSR	30 days	105 days
	Conduct confirmatory survey (if necessary)	60 days	165 days
	Inform licensee of license termination	45 days	210 days

Staff Interactions with Licensees

Introduction

The Office of Nuclear Material Safety and Safeguards (NMSS), Division of Waste Management, has instituted several project management measures to ensure prompt review of licensing action requests. This DWM internal procedure has been developed to further clarify the current process for DWM staff interactions with the licensee (new application, amendment, or renewal).

Prioritization

- Work in DWM is prioritized based on (1) safety issues of operating facilities and facilities in decommissioning and reclamation (2) new applications and license renewals (3) routine license amendments that allow flexibility in licensed activities, and (4) other work.

- It is the responsibility of the appropriate Section Chief or Team Leader, in consultation with the Branch and Division management, to prioritize work in accordance with this internal procedure. The Section Chief or Team Leader will assign a specific review team for each application.

Application

- The Project Manager (PM) is the primary point-of-contact for all licensing-related communications with the licensee. In the event the assigned PM is not available, a backup PM may be substituted on a case-by-case basis.

- The PM will arrange and chair pre-license amendment application meetings with a licensee, when these are held.

- During a pre-application meeting, the PM should inform the licensee that the licensee should provide a written statement as to whether the appropriate NRC guidance (e.g. the draft Regulatory Guide for license termination) was followed in developing its application and safety analysis report. This statement should also include a description of any deviations from the guidance taken by the licensee. Additionally, the PM should inform the licensee of the elements of this procedure during the pre-application meeting.

- The PM will ensure the expedited processing of incoming licensing actions by following NMSS Policy and Procedures Letter 1-51, "Policy and Criteria for Initial Processing of Incoming Licensing Actions."

  This policy requires a general acceptance review within 30 days of receipt of an application. While primarily an administrative review, the general acceptance review includes, but is not limited to, the following (1) legibility of drawings, (2) general adequacy of information, (3) proprietary information, and (4) obvious technical inadequacies. The objective of the acceptance review is to verify that the application contains sufficient

information before staff begins an in-depth technical review using the formal regulatory guidance.

The assigned technical reviewers shall follow the applicable guidance in the Decommissioning Handbook and other formal guidance. The PM will monitor the project to ensure that the guidance and procedures are being followed by the assigned technical reviewers.

The Decommissioning Handbook and other guidance provides guidance to DWM staff reviewers and indirectly provide guidance to licensees on the content of their applications. The SRP objectives are to (1) summarize the technical positions acceptable for meeting the regulatory requirements for application approval; (2) describe the procedures by which the DWM staff determines that these requirements have been satisfied; and (3) documents the practices developed by the staff in previous reviews of applications. These documents assist in ensuring the quality and consistency of staff reviews and in establishing well-defined bases from which to evaluate proposed changes in the scope of the reviews. Deviations from following the formal staff guidance may be done on a case-by-case basis, provided approval by the appropriate Branch Chief is obtained and the review is documented.

- The PM is responsible for written communications with the licensee.

  The PM, in conjunction with the associated technical reviewers and the LA, will prepare all written correspondence with the licensee, including, but not limited to, general correspondence, requests for additional information, safety evaluation reports, and licenses.

- The PM, in conjunction with the appropriate LA, will ensure all correspondence is docketed.

  Receipt of correspondence from a licensee, including facsimiles, by any DWM staff member will be provided to the appropriate PM/LA for docketing.

Requests for Additional Information

The PM and all associated technical reviewers should be aware of the following:

- NMSS/DWM management has indicated very strongly to the industry that improved performance on their part, in relation to the quality of submittals, is required. DWM staff members should reiterate this message as often as is warranted.

- With Branch Chief approval, in consultation with DWM management, partial or incomplete applications or RAI responses will not be reviewed. The licensee will be advised by telephone, and subsequently in writing, of the basis for this determination.

- If the staff's review requires additional licensee information, RAIs will be issued in a standard format in accordance with Branch guidelines.

This RAI includes a description of the information needed, the regulatory basis, and the technical and safety basis. The objective of using and RAI standard format is to ensure that each RAI item is unambiguous and focused on a regulatory or safety issue.

- Each significant RAI should be discussed in a meeting open to the public and chaired by the PM to assure that the licensee understands the staff's expectations regarding the RAI.

- The NRC's goal is to see improvement in amendments such that no RAI has to be issued. One round of RAIs and licensee responses (perhaps two) will be considered acceptable, but staff will (1) expect a prompt (<90 day) response from the licensee and (2) slip the review schedule accordingly if beyond 90 days.

  The licensee will be notified of this expectation/warning in the RAI cover letter. The licensee will also be advised that the extent of the slip in the staff's resumption of the review may exceed the slip in the licensee' response time.

- When more than two rounds of RAIs and responses are needed, with DWM Director approval, the staff will (1) identify its positions and concerns, and (2) suspend further technical review pending certification of application sufficiency by the licensee and its respective Owner's Group or other independent third party. The licensee will be notified of this action in writing as soon as possible.

Style and Format for Requests for Additional Information

The DWM staff reviews and evaluates the analysis and design of uranium recovery, decommissioning, and high-level waste facilities to determine technical adequacy and compliance with regulatory requirements. Requests for additional information (RAI) to any license or application should follow the following style and format as outlined below in order to ensure proper communications as outlined in NRC policy requirements.

RAIs related to the technical adequacy of the document under review should state all relevant problems and issues to be resolved prior to approval in a manner that is clear, concise, and consistent with the regulations and good engineering practice. This is considered primarily an exchange of technical information through which the staff elicits the information necessary for it to determine if the licensee has demonstrated compliance with the regulations. The staff may provide further supporting information depending upon the complexity of the request.

During the technical review, some RAIs may be related to an apparent failure to meet regulatory requirements, which must be satisfied prior to reaching a licensing decision. In this case, the RAI should identify the specific section of the regulations, and other supporting documents (Regulatory Guides, SRP, NUREGs, ASME/ASTM codes) that relate to good engineering in support of meeting the regulations. In this type of item, it is expected that supporting information will be provided, as necessary, both from a technical perspective and a regulatory one.

For major licensing actions, such as the approval of a decommissioning plan for a complex site, RAIs will be delineated by chapter and section of the plan. A general regulatory applicability statement (example given below) will be provided for each topical area. The general applicability statement will apply to all items in that area and will reference the regulatory requirements applicable to that topic. Each request will have an action verb and an object which will clearly and concisely identify the information requested. Further technical information will be provided in a separate paragraph for that item, if necessary. If an item requires further regulatory citations, it will be provided in the additional information paragraph.

Examples of action verbs that elicit knowledge, comprehension, application, analysis, synthesis, and skills are:

analyze	assess	attach	choose
clarify	classify	combine	compare
conclude	contrast	construct	defend
define	demonstrate	determine	describe
differentiate	discuss	distinguish	establish
evaluate	explain	find	identify
illustrate	indicate	justify	label
list	measure	name	perform
plan	position	provide	rate
reproduce	resolve	revise	select
specify	summarize	support	show
state	turn	translate	use

Example General Applicability Statement

This document, titled Request for Additional Information (RAI), contains a compilation of additional information requirements, identified to-date by the U.S. Nuclear Regulatory Commission staff, during its review of the licensee's amendment application and Safety and Environmental Report. NUREG [_____], and Regulatory Guide [_____] for [_____ ____] was used to review the application.

Each individual RAI describes information needed by the staff for it to complete its review of the application and to determine whether the licensee has demonstrated compliance with the regulatory requirements. Where and individual RAI relates to the licensee's apparent failure to meet one or more regulatory requirements, or where an RAI specifically focuses on compliance issues associated with one or more specific regulatory requirements (e.g., specific design criteria or accident conditions), such requirements will be specified in the individual RAI.

GUIDANCE DOCUMENT

FOR

STREAMLINING THE

URANIUM RECOVERY PROGRAM

DIVISION OF WASTE MANAGEMENT

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

January 8, 1999

1.0 INTRODUCTION TO STREAMLINED URANIUM RECOVERY LICENSING

NRC's regulations in Title 10 of the Code of Federal Regulations, Part 40 (10 CFR Part 40) set forth the technical and financial criteria for the recovery of natural uranium through milling and in situ extraction techniques and the disposition of associated waste materials. These activities are licensed, either combined or separately, as a source or a byproduct materials license. In addition, under Section 83(c) of the Atomic Energy Act (AEA), the NRC must determine that all requirements are met before terminating a license for a uranium mill undergoing reclamation. These regulations are designed to ensure that licensees operate and decommission their facilities in a safe and timely manner, and that they set aside adequate funds to ensure that the decommissioning and reclamation can be accomplished in the event the licensee is unable to accomplish those activities. NRC's responsibility is to ensure that these regulations are met by licensees. The uranium recovery program typically consists of new applications, and amendments to licenses that authorize operational and decommissioning activities, and the termination of a license once residual radioactivity is cleaned up to levels that meet NRC's regulations. In addition to the public health and safety reviews associated with licensing actions, the NRC licensing program must address National Environmental Policy Act (NEPA) responsibilities that are set forth in 10 CFR Part 51.

The purpose of this document is to provide staff in the uranium recovery program with guidance for conducting streamlined licensing reviews. A streamlined review, in addition to accomplishing the necessary health and safety review objectives, also completes a licensing decision in an efficient manner that conforms to the NRC's regulatory framework and a period of time that meets the applicant's needs. A streamlined review process imposes discipline, encourages communication (both formal and informal) between NRC and the applicant, and establishes schedules for all parties. This process is intended to facilitate staff reviews and licensing decisions in accordance with defined and agreed upon schedules. This guidance supplements existing guidance principally contained in the Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act (NUREG-1620) and the Standard Review Plan for *In Situ* Leach Uranium Extraction License Applications (NUREG-1569).

This guidance is applicable to all forms of uranium recovery licensing actions such as applications for new facilities, renewals, amendments, reclamation plans, and license terminations. This procedure does not apply to the inspection or enforcement programs. This procedure does not at this time address other related "streamlining" initiatives that are being investigated now, such as the Commission-directed "pilot program."

A review of any licensing action is not intended to be an exhaustive evaluation of all aspects of decommissioning a facility. Specific information about implementation of the program outlined in an application and/or a decommissioning plan is obtained through the NRC review of procedures and operations done as part of the inspection function. The detailed steps of a licensing review are discussed later in this guidance, along with a generic schedule for nearly all expected uranium recovery decommissioning licensing actions.

2.0 REGULATORY PHILOSOPHY

Streamlining and NRC's Safety Philosophy

Since the Atomic Energy Act of 1954 was passed, the Commission has been engaged in a continuing process of interpreting and applying the agency's basic responsibilities as defined by that law: viz., to "protect public health and safety," "assure the common defense and security," "minimize danger to life or property," and "provide adequate protection." These terms are not defined in the AEA, nor are they self-explanatory. The basic NRC Safety Philosophy is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

> "LICENSEE RESPONSIBILITY embodies the principal that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing, and other activities on those areas where the need, and the likely safety and safeguards benefit, are greatest."

To state it more succinctly, the safe operation of any nuclear facility is the responsibility of the licensee. This philosophy is an important foundation for how NRC staff is to conduct their reviews in general, and streamlined licensing reviews in particular. Streamlining begins with a recognition of NRC's regulatory role in relation to its licensees, i.e., that licensees have the primary responsibility for ensuring the safety of nuclear facilities.

Implementing this philosophy, means the following:

- NRC does not select sites or designs or participate with licensees or applicants in selecting proposed sites or designs.

- NRC's role is not to monitor all licensee activities but to oversee and audit them. NRC should evaluate whether the proposal meets the applicable regulations based on a review of what is in the application. Staff audit calculations should be used in very limited situations such as unique proposals involving new methods or assumptions. Otherwise, the NRC staff should review the application to ensure that assumptions are justified, methods used are acceptable and applicable over the range presented in the application, the model was properly applied, and the results are acceptable. Staff can and should do quick, bounding calculations; however, in-depth, detailed performance assessments can be limited to a very few applications. Figure 1 shows the relationship of the level of detail to licensing reviews and inspections.

- The three outcomes available to NRC at the conclusion of a licensing review are: (1) grant the application; (2) grant the application subject to certain conditions agreed upon by the licensee; or (3) deny the application. Other than rejecting an

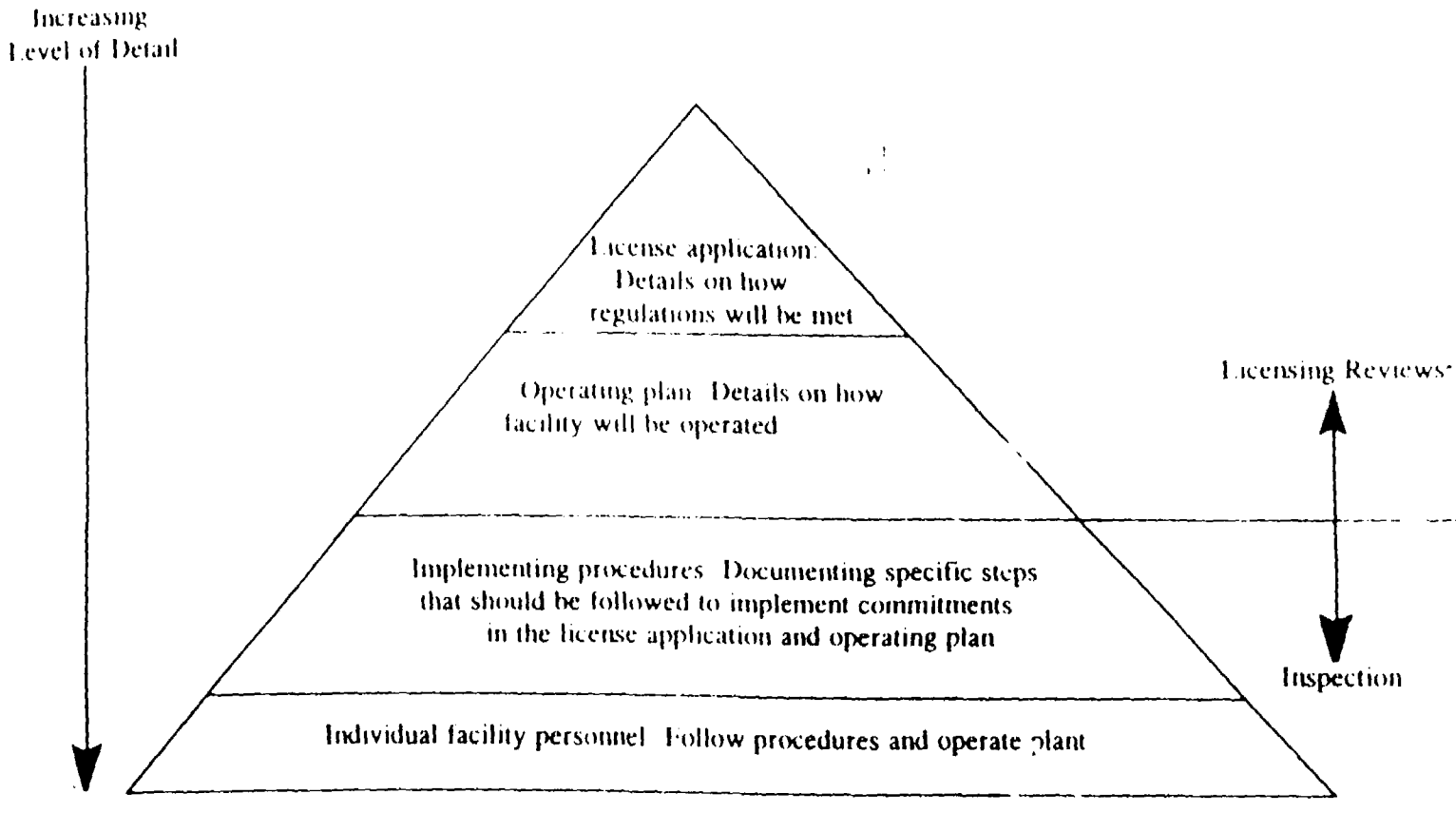

Figure 1 Outline of Licensing versus Inspection Time Frames

applicant or licensee's proposal, NRC has no power to compel a licensee to come forward or to require a licensee to prepare a totally different proposal.

NRC's regulatory role in any licensing action is to apply the applicable regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved. The burden of proof is on the applicant or licensee to show that the proposed action is safe, and regulations are met, and to ensure continued compliance with the regulations.

In conducting its reviews, NRC is looking for regulatory truth (i.e., whether there is demonstration that an applicant's proposed approach meets the codified requirements), not scientific precision (i.e., having complete understanding and answers for all issues that could be raised concerning a proposal, including those not related to health and safety).

This basic regulatory philosophy is applied in both NRC safety and environmental reviews. For safety reviews, the NRC staff should examine whether applicant and licensee proposals are acceptable. Because of this, NRC staff should ensure that they do not look to drive licensees to the best possible solution. Basically, if a proposal meets the applicable regulations, the NRC staff has no basis for requiring something different. To do so would be imposing a requirement on a licensee. This is normally done through the issuance of an order with hearing rights according to 10 CFR Part 2, Subpart L.

In conducting environmental reviews, the National Environmental Policy Act of 1969 requires an evaluation of the environmental impacts. However, unlike the safety review discussed earlier, there are no specific requirements that determine if a proposal is environmentally acceptable. Consistent with 10 CFR 51.21, all licensing actions require an environmental assessment unless the NRC is completing either an Environmental Impact Statement, or the staff has found that the action is categorically excluded according to one of the criteria found in 10 CFR 51.22. For uranium recovery activities, many amendment applications meet one of the four exemptions in 10 CFR 51.22(c)(11), and thus are categorically excluded.

For evaluations of environmental impacts, the staff should focus its evaluation efforts on the proposed licensing action. The Commission position in the Statement of Consideration for Part 51 is that the alternative analysis performed in support of any environmental impact analysis should be completed by using reconnaissance-level information. This type of information is generally available and does not require any or much site-specific work, such as site characterization, to obtain. The Commission's and CEQ's reason for using reconnaissance-level information is that although it may be possible to optimize designs or provide more detailed impact analysis, it is highly unlikely that a detailed examination of the alternatives would reveal any significant environmental impacts that would escape a review done with reconnaissance-level information.

This is an important point because the NRC staff can only deny an application for one of two environmental reasons. First, the environmental impacts are found unacceptable (i.e., do not comply with applicable State or Federal laws or regulations, such as the Clean Air Act), or second, one of the alternatives analyzed proves to be obviously superior. The determination of obvious superiority includes both enhanced environmental benefit at only minimal cost increases. In no instance, either with a safety or environmental review, should a reviewer

determine that alternatives that are less protective than those proposed by the applicant are acceptable (in the case of a safety review) or preferred (in the case of an environmental review). NRC staff should always operate from a position that questions are asked when more information is needed to justify the proposal. However, the NRC staff should never tell licensees how they can do less or back off from what is proposed and still meet the regulations. To say it more succinctly; "Always ask them to do more to meet requirements, but never tell them to do less." If there is an issue associated with protection of public health and safety that requires prompt action from the licensee, NRC staff should prepare an immediately-effective order under 10 CFR 2.202(a)(5).

In pre-licensing meetings, for example, it is appropriate for staff to inform licensees when they are applying the regulations inappropriately (submitting an environmental report, for example, when a categorical exclusion is acceptable).

Streamlining and Principles of Good Regulation

Streamlining of the materials licensing process is also consistent with the Commission's "Principles of Good Regulation." The following excerpts from these principles bear improving the efficiency of materials licensing reviews:

> "EFFICIENT. The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities . . . Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay."
>
> "CLEAR. . . . There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions [e.g., RAIs] should be readily understood and easily applied."
>
> "RELIABLE. . . Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes."

The remaining sections of this guidance discuss the details of how reviews should be conducted. They include a discussion on how staff should approach reviews, what the format of the various products such as safety evaluation reports, environmental assessments, and requests for additional information (RAIs) should look, and generic schedules for various types of licensing actions. They are developed consistent with the regulatory framework discussed above.

3.0 APPROACH TO STREAMLINING LICENSING REVIEWS

Several key elements or characteristics are considered necessary for effective streamlining of the licensing review process from both time-efficiency and regulatory-acceptability perspectives. These characteristics are:

- Empowered Reviewers

  Reviewers are given the freedom, within the agency's regulatory framework covering a licensing action, to control the conduct of the review, and to make licensing decisions without undue delay. Reviewers are able to exercise a high degree of independence to work toward timely resolution of technical issues. Complete licencing decisions in a period of time that meets the applicant's needs.

- Defined Goals

  Regulations define the goals for achieving safety. The Principles themselves are broad goals to be achieved that relate to safety, efficiency, and dependability of NRC's licensing actions. Regulations form the basis for all aspects of the licensing review, including RAIs, SERs, and environmental reviews. Licensing decisions are based on reasonable assurance of no undue risk to public health, safety and the environment. Applicants have a reasonable expectation of timeliness.

- Control over RAIs

  Agency positions are to be readily understood by licensees, and should be consistent with written regulations. Preliminary Safety Evaluation Reports should be developed early in the review process to focus any needs for additional information and assure all technical areas of concern are adequately addressed by the applicant. Licensing will be constrained by the areas of review defined by the Standard Review Plans. The goal of any licensing review is for no RAIs; however, if additional information is needed, the request(s) should be limited to one round of RAIs. The requests should be stated concisely, focused, and clearly convey what information is required.

- Defined Rules of Engagement

  Staff's review schedules and expectations of the applicant's response timeliness and quality will be defined and agreed upon by both parties. Applicants will be informed on how their application will be treated and the new (streamlined) licensing program will be explained.

- Assessment of Complexity and Applicability of Existing Precedents, Policy, Regulations and Guidance

  Staff will examine each licensing proposed action and plan for only the necessary and sufficient procedures to act on it. For complex cases or cases with unusual public, State, or Congressional interest, it may be appropriate to conduct public meetings to discuss the staff's plans and

decisions, for example. Simpler cases can follow a more streamlined process, consistent with the minimum required by law and regulation.

- Use of Licensing Review Teams
  When appropriate, multi disciplinary review teams are formed to conduct simultaneous reviews of various technical areas of an applicant's proposal.

- Discipline
  These procedures for streamlining provide discipline for an improved licensing process for the prompt resolution of technical issues. Reviewers should not enter into interrogatories on obviously unacceptable proposals. If issues cannot be resolved in a timely manner, the issue must be escalated to higher management levels within the NRC and the applicant's organization.

- Early Meetings
  Regulatory decisions are to be made without undue delay and to be promptly administered. Early meetings also contribute to understanding of NRC's positions, and help to clarify the information that is needed to resolve issues. Meet with applicants or licensees early in the review process to discuss preliminary findings and outstanding issues

Four primary milestones must be systematically completed in order to finish a review of an applicant's licensing action request in a time-efficient and regulatory-defensible manner. These milestones and their objectives listed below, should be conducted in accordance with the characteristics of the streamlined licensing approach:

- Acceptance Reviews
  determines the completeness of the applicant's submitted materials, whether sufficient information is provided to support a detailed review, and the schedule of subsequent milestones

- Detailed Reviews
  determines the safety and environmental acceptability of the proposed action, based on technical reviews of the applicant's information and demonstrations of compliance with regulatory requirements

- Requests for Additional Information
  documents insufficient or inadequate information submitted by the applicant and communicates staff's requests for what additional information is needed to address the identified deficiencies

- Safety and Environmental Review Reports (SER, EA, or EIS)
  communicates staff's position on the safety and environmental acceptability of the applicant's request, which forms the basis of the subsequent licensing action

The acceptance review serves as the initial screening of an applicant's request and provides the initial estimate for allocating staff resources to support a complete licensing review. An applicant's request must provide sufficient information, both quality and quantity, by either inclusion or reference, to address the regulatory requirements of the proposed action. Acceptance reviews should be performed on all incoming requests for license amendments, license renewals, and new license applications in the Uranium Recovery Program. For applications that do not meet this minimum standard, the applicant should be informed of the deficiencies, and told that the NRC does not consider the application complete enough to warrant a review. Accepting a substandard request for the detailed review places a timely and an effective licensing review in jeopardy, because of the high potential for multiple RAIs while the applicant refines its analysis.

Completing the other milestones is generally sequential, however, each milestone is not independent from the others. For example, the SER and EA reports should be initiated in a preliminary form during the early stages of the Detailed Review. The preliminary reports should follow the appropriate SRP format, and be tied directly to a specific regulation. This allows the reviewer(s) to focus on regulatory-significant safety and environmental issues and reduces the potential likelihood of significant issues going unaddressed during subsequent milestones. Any deficiencies identified during the detailed review can be documented and highlighted in the preliminary report, along with what information would be required to address the deficiency.

These deficiencies documented in the preliminary reports constitute the foundation for the official Requests for Additional Information (RAIs), which will be communicated to the applicant in writing. The goal of conducting the detailed review in this manner is to limit the RAIs to one round of staff request and applicant response.

Clear and early communication of potential problems or deficiencies is crucial for effective completion of the licensing review. Reviewers should be "empowered" to initiate early communication with applicants' by using teleconferences or videoconferences as a means of verifying the staff's understanding of the supplied information and determine which potential issues could be resolved by the applicant supplying additional information. Under the provisions of 10 CFR 2.101, these communications can occur even before an application is submitted. The staff should also determine if the meeting should be conducted at the site to better understand the nature of the application, if site conditions will be a factor in the final decision. Staff should remember that meetings with applicants' or licensee's are open to the public and must be noticed as such. Procedures outlining staff interactions with applicants are provided in Attachment 1.

Early communication with the applicant should also include discussions and agreement on a schedule for subsequent milestones in the review process. This discussion and agreement constitute the official "rules of engagement" for the remaining phases of the licensing action which must be communicated in writing at the completion of the acceptance review and the RAIs, if necessary. The consequences of not meeting the agreed schedule must be clearly communicated to the applicant in the RAI cover letter.

If the applicant does not respond in that time period, or provides answers that are incomplete to finish the review, the application should be considered for denial under the provisions of 10 CFR 2.108. If such a denial is issued, then the applicant should be informed of the hearing

rights available to it under the provisions of 10 CFR Part 2, Subpart L. In any event, the applicant's failure to respond within the specified time frame will at least result in the proposed action losing its place in the review "queue."

Empowerment also requires that reviewers work with a high degree of independence such that unresolved issues are communicated to the appropriate licensee management level to assure timely resolutions. If reviewers work within the regulatory framework outlined in Section 2 of this guidance, they should be able to independently conduct a review with little management involvement that complies with programmatic needs and regulatory requirements.

If reviewers find that timely resolution is not being achieved even after contact with licensee management, the reviewers should raise a concern to NRC management. This helps ensure that NRC management is responsive to the issues, and is focused on getting reviews done in a timely manner.

All official requests for information, schedule agreements, and the applicant's responses must be communicated in writing in order to eliminate potential misunderstandings from verbal discussions, provide an official record of staff/applicant interactions, and document the applicant's commitments for inclusion in the licensing documents. As a goal, written communications should be in a style and level of technical detail such that an informed member of the general public could understand the document. A good "rule-of-thumb" to gage whether a document is targeted to an informed member of the public is to ask, "Could this document be read and understood by a high school graduated who has taken chemistry, mathematics and physics?" Issuing documents that are difficult to read and understand do not promote effective and timely licensing reviews.

4.0 FORMAT AND CONTENT OF DOCUMENTS

Correspondence and documents from each of the licensing review milestones should be logically organized and contain adequate information to convey NRC's position and requirements in a simple, clear and concise manner.

The acceptance review does not determine the technical adequacy of the submitted information, unless the Commission decides to determine the acceptability of an application on its technical adequacy, as well as completeness (for example, commercial waste disposal facilities).

The applicant must be notified in writing of the acceptance review determination, within 30 days of receipt of the request. The acceptance review is documented by a brief, one to two page letter recommending acceptance for initiating the detailed review or rejection. Upon acceptance, the letter also sets a schedule of the pending detailed review, including intermediate milestones and the anticipated completion date. The letter should include a disclaimer stating that the additional information requests may result from the detailed review and the projected review schedule is contingent upon the applicant supplying high-quality, timely responses to any information requests. The letter must also inform the applicant that failure to respond to additional information requests within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). The only exception to the written notification is if the detailed review of a request can be completed and the licensing action taken within 30 days.

Written requests for additional information should be focused, brief and clear. An RAI should include three parts:

- Issue
  a summary of the identified deficiency and the regulatory requirement
- Discussion
  a summary of the applicant's information or response and why it is unsatisfactory
- Action Needed
  a concise statement of what information is needed to address the deficiency

RAIs should be numbered sequentially with the numbering for an individual RAI remaining constant through the course of the licensing review. The cover letter transmitting the RAIs must include a schedule for the applicant to provide responses and the dates of the remaining milestones. The letter must also reiterate the statement from the acceptance review that failure to respond within the specified time frame may be grounds for denial of the application, in accordance with 10 CFR 2.108(a). Additional guidance for the style and format of RAIs is provided in Attachment 2.

The content of the SER and EA shall be based on the guidance provided in the appropriate SRP. The technical basis for the staff evaluations and conclusions is focused first on the safety

and environmental issues, and then on the regulatory issues. If there are limits and restrictions imposed as a condition of approval and agreed to by the applicant, they need to be addressed as requirements in the license. The technical reviewer should notify the licensing project manager as soon as practical if this is the case.

If the SER and EA are generated for amendments to licenses, the reviewer should limit the scope of the review to the topics necessary for the amendment application and make the necessary limited findings, as appropriate. The review should focus on the regulatory requirements, and determine compliance with these regulations. The safety and environmental reviews can be conducted in parallel rather than series. In some circumstances, it may be possible to complete the environmental review earlier than the safety review. When this is the case, the reviewer should complete the environmental review, and publish the results in the Federal Register.

Keep in mind that the environmental review should include any consultation with the Fish and Wildlife Service under the Endangered Species Act and the State Historic Preservation Officer under the Historic Preservation Act, and the appropriate state agency administering environmental compliance. These consultations can also be initiated in parallel during the environmental review rather than waiting for completion of the EA or EIS.

SECY-94-270 dated November 2, 1994 describes the agency policy for documenting the results of consultation with other agencies or persons on environmental assessments. Only a brief statement of the consulted agency or person's comments and the agency's response is necessary in the EA. The EA should identify the agency or person consulted, note the date of the consultation, summarize the consultation, and provide the resolution of any comments received. If the consulted agency or person made no specific comments, a simple statement to that effect, such as "no comment," "no objection," or "agreement" would be sufficient. However, if the agency or person made specific comments, these should be summarized along with the agency's response.

The format for the SER and the EA (or EIS) should customarily follow the outline of the appropriate SRP for major actions, and the examples given in the attached appendix for smaller more routine actions. The findings that have been made, as a result of the detailed review, will be stated in the SER or EA at the conclusion of each section. If there are limiting conditions that need to be imposed, they should be highlighted for inclusion in the license. In all cases, the limiting conditions that are enumerated in the license shall be identified in the SER or EA.

5.0 GENERIC LICENSING SCHEDULES

The schedules laid out below are intended to be goals for completing licensing actions. They are not intended are rigid milestones that must be met. Individual circumstances may dictate a different schedule depending on the particular circumstances like availability of staff.

Generic Licensing Schedule		
Licensing Action	**Duration**	**Cumulative**
Simple Amendments (routine surety updates at non operational facilities, no deficiencies)	30 days	30 days
Standard Amendments (surety updates at operational facilities, no deficiencies)	60 days	60 days
Major Amendments (new ISL facilities, reclamation plans, ground-water cleanup plans)		
Safety Review		
Acceptance Review	30 days	30 days
Early SER and Requests for Additional Information (RAIs)	30 days	60 days
Applicant Response	60 days	120 days
Complete Technical Review (final SER)	30 days	150 days
Complete Licensing Action	30 days	180 days
Environmental Review		
Consult with U.S. Fish and Wildlife Service (FWS)[1]	60 days	60 days
Consult with State Historic Preservation Officer (SHPO)	60 days	60 days
Complete Environmental Assessment[2]	60 days	60 days
Consult with State Environmental Officer (SEO)	15 days	75 days

[1]Undertake consultation as needed. Otherwise get letter from Service that no impact will occur to endangered species.

[2]Do not complete this step if action is categorically excluded or requires and Environmental Impact Statement.

Generic Licensing Schedule

Licensing Action	Duration	Cumulative
Issue Finding of No Significant Impact[3]	30 days	105 days
Major Application with Environmental Impact Statement (new mills, commercial disposal sites, special cases)		
Safety Review	(Same as above)	
Environmental Review		
Consult with FWS	60 days	60 days
Consult with SHPO	60 days	60 days
Consult with SEO	60 days	60 days
Complete Draft Environmental Impact Statement (EIS)	120 days	180 days
Issue for public comment, evaluate public comments	120 days	300 days
Compete Final EIS	60 days	360 days

[3]Complete only if previous step completed.

Staff Interactions with Applicants

Introduction

The Office of Nuclear Material Safety and Safeguards (NMSS), Division of Waste Management, has instituted several project management measures to ensure prompt review of licensing action requests. This DWM internal procedure has been developed to further clarify the current process for DWM staff interactions with the applicant (new application, amendment, or renewal).

Prioritization

- Work in DWM is prioritized based on (1) safety issues of operating facilities and facilities in decommissioning and reclamation (2) new applications and license renewals (3) routine license amendments that allow flexibility in licensed activities, and (4) other work.

- It is the responsibility of the appropriate Section Chief or Team Leader, in consultation with the Branch and Division management, to prioritize work in accordance with this internal procedure. The Section Chief or Team Leader will assign a specific review team for each application.

Application

- The Project Manager (PM) is the primary point-of-contact for all licensing-related communications with the applicant. In the event the assigned PM is not available, a backup PM may be substituted on a case-by-case basis.

- The PM will arrange and chair pre-application meetings with the applicant.

  For commercial applications, the PM, in conjunction with the appropriate Licensing Assistant (LA), will ensure that a docket number is assigned and a TAC number is opened as fee billable during the pre-application phase. The potential applicant should be informed of this, prior to the first pre-application meeting.

  During a pre-application meeting, the PM should inform the applicant that the applicant should provide a written statement as to whether the appropriate standard review plan (SRP) was followed in developing its application and safety analysis report. This statement should also include a description of any deviations from the SRPs taken by the applicant. Additionally, the PM should inform the applicant of the elements of this procedure during the pre-application meeting.

- The PM will ensure the expedited processing of incoming licensing actions by following NMSS Policy and Procedures Letter 1-51, "Policy and Criteria for Initial Processing of Incoming Licensing Actions."

  This policy requires a general acceptance review within 30 days of receipt of an application. While primarily an administrative review, the general acceptance review includes, but is not limited to, the following (1) legibility of drawings, (2) general

adequacy of information, (3) proprietary information, and (4) obvious technical inadequacies. The objective of the acceptance review is to verify that the application contains sufficient information before staff begins an in-depth technical review using the SRPs.

- The assigned technical reviewers shall follow the applicable SRP(s). The PM will monitor the project to ensure that the SRP(s) are being followed by the assigned technical reviewers.

  The SRPs provide guidance to DWM staff reviewers and indirectly provide guidance to applicants on the content of their applications. The SRP objectives are to (1) summarize the technical positions acceptable for meeting the regulatory requirements for application approval; (2) describe the procedures by which the DWM staff determines that these requirements have been satisfied; and (3) documents the practices developed by the staff in previous reviews of applications. The SRPs assist in ensuring the quality and consistency of staff reviews and in establishing well-defined bases from which to evaluate proposed changes in the scope of the reviews. Deviations from following the SRPs may be done on a case-by-case basis, provided approval by the appropriate Branch Chief is obtained and the review is documented.

- The PM is responsible for written communications with the applicant.

  The PM, in conjunction with the associated technical reviewers and the LA, will prepare all written correspondence with the applicant, including, but not limited to, general correspondence, requests for additional information, safety evaluation reports, and licenses.

- The PM, in conjunction with the appropriate LA, will ensure all correspondence is docketed.

  Receipt of correspondence from a current or potential applicant, including facsimiles, by any DWM staff member will be provided to the appropriate PM/LA for docketing.

Requests for Additional Information

The PM and all associated technical reviewers should be aware of the following:

- NMSS/DWM management has indicated very strongly to the industry that improved performance on their part, in relation to the quality of submittals, is required. DWM staff members should reiterate this message as often as is warranted.

- With Branch Chief approval, in consultation with DWM management, partial or incomplete applications or RAI responses will not be reviewed. The applicant will be advised by telephone, and subsequently in writing, of the basis for this determination.

- If the staff's review requires additional applicant information, RAIs will be issued in a stand format in accordance with Branch guidelines.

This RAI includes a description of the information needed, the regulatory basis, and the technical and safety basis. The objective of using and RAI standard format is to ensure that each RAI item is unambiguous and focused on a regulatory or safety issue.

- Each significant RAI should be discussed in a meeting open to the public and chaired by the PM to assure that the applicant understands the staff's expectations regarding the RAI.

- The NRC's goal is to see improvement in new applications and amendments such that no RAI has to be issued. One round of RAIs and applicant responses (perhaps two) will be considered acceptable, but staff will (1) expect a prompt (<90 day) response from the applicant and (2) slip the review schedule accordingly if beyond 90 days.

  The applicant will be notified of this expectation/warning in the RAI cover letter. The applicant will also be advised that the extent of the slip in the staff's resumption of the review may exceed the slip in the applicant' response time.

- When more than two rounds of RAIs and responses are needed, with DWM Director approval, the staff will (1) identify its positions and concerns, and (2) suspend further technical review pending certification of application sufficiency by the applicant and its respective Owner's Group or other independent third party. The applicant will be notified of this action in writing as soon as possible.

Style and Format for Requests for Additional Information

The DWM staff reviews and evaluates the analysis and design of uranium recovery, decommissioning, and high-level waste facilities to determine technical adequacy and compliance with regulatory requirements. Requests for additional information (RAI) to any license or application should follow the following style and format as outlined below in order to ensure proper communications as outlined in NRC policy requirements.

RAIs related to the technical adequacy of the document under review should state all relevant problems and issues to be resolved prior to approval in a manner that is clear, concise, and consistent with the regulations and good engineering practice. This is considered primarily an exchange of technical information through which the staff elicits the information necessary for it to determine if the applicant has demonstrated compliance with the regulations. The staff may provide further supporting information depending upon the complexity of the request.

During the technical review, some RAIs may be related to an apparent failure to meet regulatory requirements, which must be satisfied prior to reaching a licensing decision. IN this case, the RAI should identify the specific section of the regulations, and other supporting documents (Regulatory Guides, SRP, NUREGs, ASME/ASTM codes) that relate to good engineering in support of meeting the regulations. In this type of item, it is expected that supporting information will be provided, as necessary, both from a technical perspective and a regulatory one.

For major licensing actions, such as new applications or renewals, RAIs will be delineated by chapter and section, preferably following the organization of the SRP. A general regulatory applicability statement (example given below) will be provided for each topical area. The general applicability statement will apply to all items in that area and will reference the regulatory requirements applicable to that topic. Each request will have an action verb and an object which will clearly and concisely identify the information requested. Further technical information will be provided in a separate paragraph for that item, if necessary. If an item requires further regulatory citations, it will be provided in the additional information paragraph.

Examples of action verbs that elicit knowledge, comprehension, application, analysis, synthesis, and skills are:

analyze	assess	attach	choose
clarify	classify	combine	compare
conclude	contrast	construct	defend
define	demonstrate	determine	describe
differentiate	discuss	distinguish	establish
evaluate	explain	find	identify
illustrate	indicate	justify	label
list	measure	name	perform
plan	position	provide	rate
reproduce	resolve	revise	select
specify	summarize	support	show
state	turn	translate	use

Example General Applicability Statement

This document, titled Request for Additional Information (RAI), contains a compilation of additional information requirements, identified to-date by the U.S. Nuclear Regulatory Commission staff, during its review of the applicant's application and Safety and Environmental Report. NUREG [_____] Standard Review Plan for [_____] was used to review the application. This RAI follows the same format as NUREG [_____].

Each individual RAI describes information needed by the staff for it to complete its review of the application and to determine whether the applicant has demonstrated compliance with the regulatory requirements. Where and individual RAI relates to the applicant's apparent failure to meet one or more regulatory requirements, or where an RAI specifically focuses on compliance issues associated with one or more specific regulatory requirements (e.g., specific design criteria or accident conditions), such requirements will be specified in the individual RAI.