NUREG-1541

Process and Design for Consolidating and Updating Materials Licensing Guidance

Draft Report for Comment

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

J. E. Whitten, P. C. Valdez, K. D. Brown, R. A. Rathbun

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Manuscript Completed: April 1996
Date Published: April 1996

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Abstract

This report describes the concept and approach for developing the Materials Electronic Library (MEL). The Business Process Redesign team for the licensing of materials conceived, as an integral part of its vision for the redesign of this licensing process, the idea for MEL. To establish MEL, the NRC will consolidate and update numerous regulations and policy and guidance documents supporting the materials licensing process into a single, comprehensive electronic repository for use by the NRC, Agreement and non-Agreement States, licensees, applicants, and the public.

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FOREWORD

The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) techniques to redesign its material licensing process to achieve an order of magnitude improvement in speed, while maintaining or improving the level of public safety; see NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," for additional details. Fundamental to the success of the new licensing process is the consolidating and updating of an extensive number and variety of guidance documents that support the material licensing process into a single comprehensive repository called the Materials Electronic Library (MEL). This report describes the approach and conceptual design of MEL and is the first of a planned series of staff reports that the NRC will publish (NUREG series) on MEL. These reports are intended to inform the reader about the MEL project, provide an ongoing status report, and request comments on various aspects of the project. The project's end result will be an electronic library accessible by the NRC's staff and managers, Agreement and non-Agreement States, licensees, applicants, and the public. The MEL concept, design, and approach are a radical departure from today's way of doing business.

Over the years, the NRC has used a number of regulatory guides, policies and procedures, standard review plans, and other documents to communicate the NRC's policy to licensees and to the NRC staff. Each of these documents was written to address either a particular use of radioactive material or a particular radiation safety issue. The net result has been a multitude of documents, many of which are now out of date, from which NRC staff and licensees must derive the requirements, policies, and materials needed for licensed activities. MEL is intended to be a simple communication vehicle that can keep up with change.

This document discusses MEL and how it was created, and seeks comments on MEL-related issues. The MEL's development strategy is a prototype of NRC's new process for developing "regulatory products." During the comment period on this document, the staff is actively seeking comments from all readers, including but not limited to, licensees, applicants, the public, and Agreement and non-Agreement States. Comments will be useful in making needed "mid-course" corrections as early as possible in the development of MEL. Comments on this draft report will be most useful if received within 90 days of its publication, but comments received after that time will also be considered if practicable.

Written comments should be addressed to: Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays.

Draft NUREG-1541 is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this draft report are provided for information and comment only. Publication of this report does not necessarily constitute NRC approval or agreement with the information contained herein.

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and Safeguards

Acknowledgments

The materials electronic library (MEL) team thanks the individuals listed on the next page for assisting in the development of MEL, including those who participated in refining the concept of the electronic library process, reviewing the initial outlines and storyboards, providing suggestions and technical input, and preparing the first draft of MEL. All participants provided valuable insights, observations, and recommendations about MEL and the diverse environments in which it must operate. The MEL team also thanks other NRC and Agreement State colleagues who provided comments, suggestions, and recommendations.

Finally, the MEL team thanks Kay Avery, Eric Bazerghi, Veronica Bellone, Judy Boykin, Mary Carnahan, David Greenwald, Karl Leatham, Johan Margono, Alyce J. Martin, Pam Miller, and Tim Woods from Computer Sciences Corporation, Joseph Klinger of the State of Illinois, Douglas R. Marco of Select Staffing Services, Dorian Conger of Conger and Elsea, Inc., and Donovan Smith and Donald Hopkins of Advanced Systems Technology, Inc., for their contributions to the development of MEL and the production of this document.

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Abbreviations

AEOD	Office of Analysis and Evaluation of Operational Data
ANSI	American National Standards Institute
BPR	Business Process Redesign
EPA	U.S. Environmental Protection Agency
GC	Gas Chromatography
HPPOS	Health Physics Positions
IAEA	International Atomic Energy Agency
MEL	Materials Electronic Library
NRC	U.S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
P&GD	Policy and Guidance Directives
R&D	Research and Development
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SNM	Special Nuclear Material
SRP	Standard Review Plan
TTC	Technical Training Center

1 Introduction

1.1 Purpose

This document describes the approach and conceptual design of the materials electronic library (MEL). The projected end result of MEL will be an electronic library accessible by NRC's staff and managers, Agreement and non-Agreement States, applicants, licensees, and the public. The MEL concept, design, and approach are a radical departure from today's way of doing business.

1.2 Background

In NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," the NRC staff discusses the methodology and findings of its effort to fundamentally redesign the materials licensing process. On the basis of the findings from the data collection phase of this effort, the Business Process Redesign (BPR) Team created a vision of the new materials licensing process which is depicted in Figure 1.1.

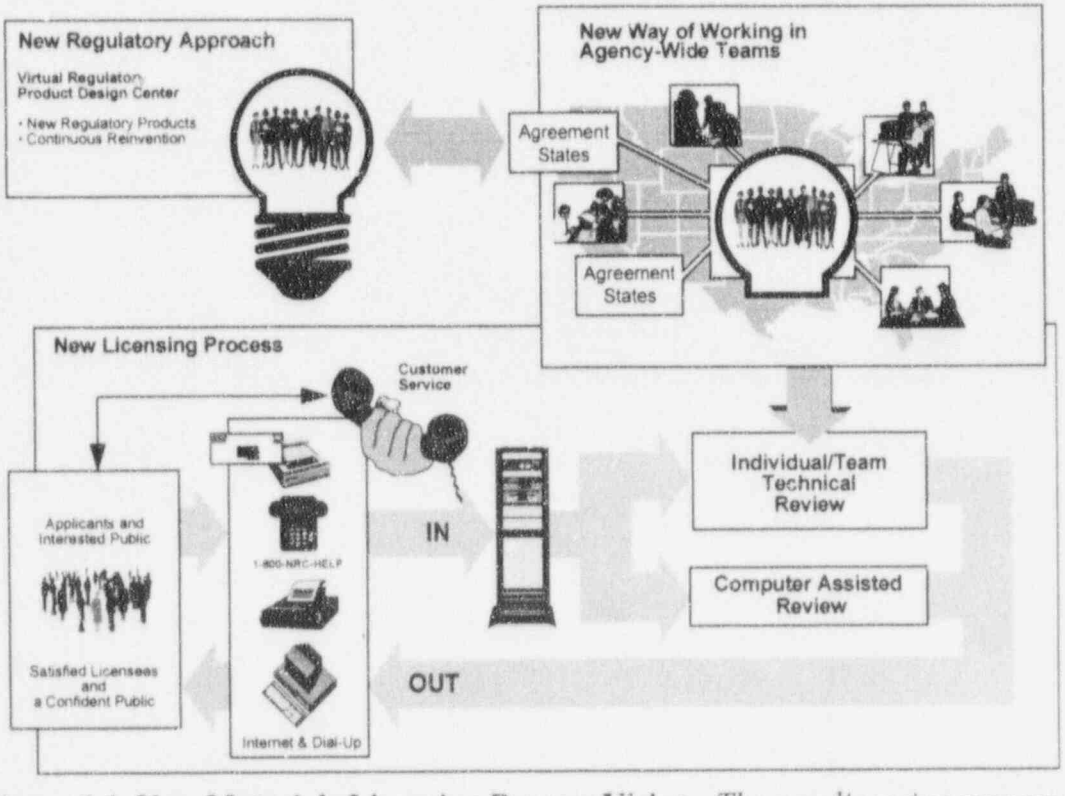

Figure 1.1 New Materials Licensing Process Vision. *The new licensing process links the materials licensing community.*

Consolidating and updating the extensive number and variety of guidance documents that support materials licensing is fundamental to the success of the new licensing process. Over the years, the NRC has used a number of regulatory guides, policies and procedures, standard review plans, and other documents to communicate the NRC's policy to licensees and to the NRC staff. Each of these documents was written to address either a particular use of radioactive material or a particular radiation safety issue. The net result has been a multitude of documents, many of which are now out of date, from which NRC staff and licensees must derive the requirements, policies, and other needed materials for carrying out licensed activities (see Figure 1.2).

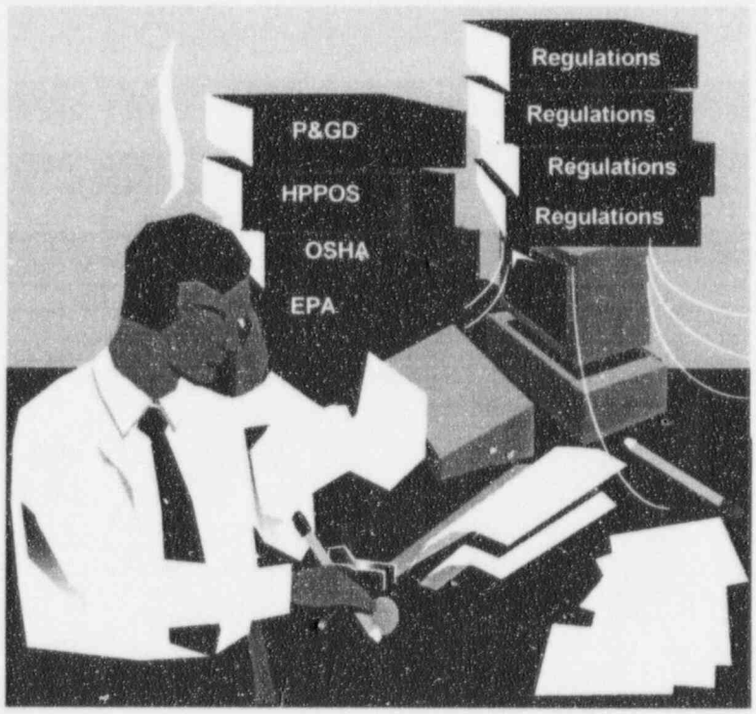

Figure 1.2 Staff Conducting Research before MEL Implementation. *A member of the NRC staff researches documents to review a materials license application.*

1.3 Objectives

The key objectives of MEL are that it be—

- the single comprehensive source of current regulatory guidance and policy information;
- accessible to all who need it, including applicants, licensees, NRC staff, Agreement and non-Agreement States, and members of the public;
- easy to use and maintain; and
- flexible to enable NRC to quickly respond to its changing regulatory environment.

Careful planning and execution are required to communicate the MEL concepts effectively to the public, applicants, licensees, Agreement and non-Agreement States, NRC managers, and materials licensing and inspection staff. As part of this communication effort, NRC plans a validation process to ensure that the conceptual design and subsequent technical approach will support the listed MEL objectives.

Presenting the conceptual design at an early stage allows the opportunity to incorporate necessary changes. During the comment period on this document, the MEL team is actively seeking comments, as described in Section 5. NRC believes that early feedback is necessary in order to optimize the final product.

1.4 What is MEL?

MEL is to be a single comprehensive repository of consolidated, current guidance and reference materials for use by applicants, licensees, the NRC staff and managers, Agreement and non-Agreement States, and the public (see Figure 1.3).

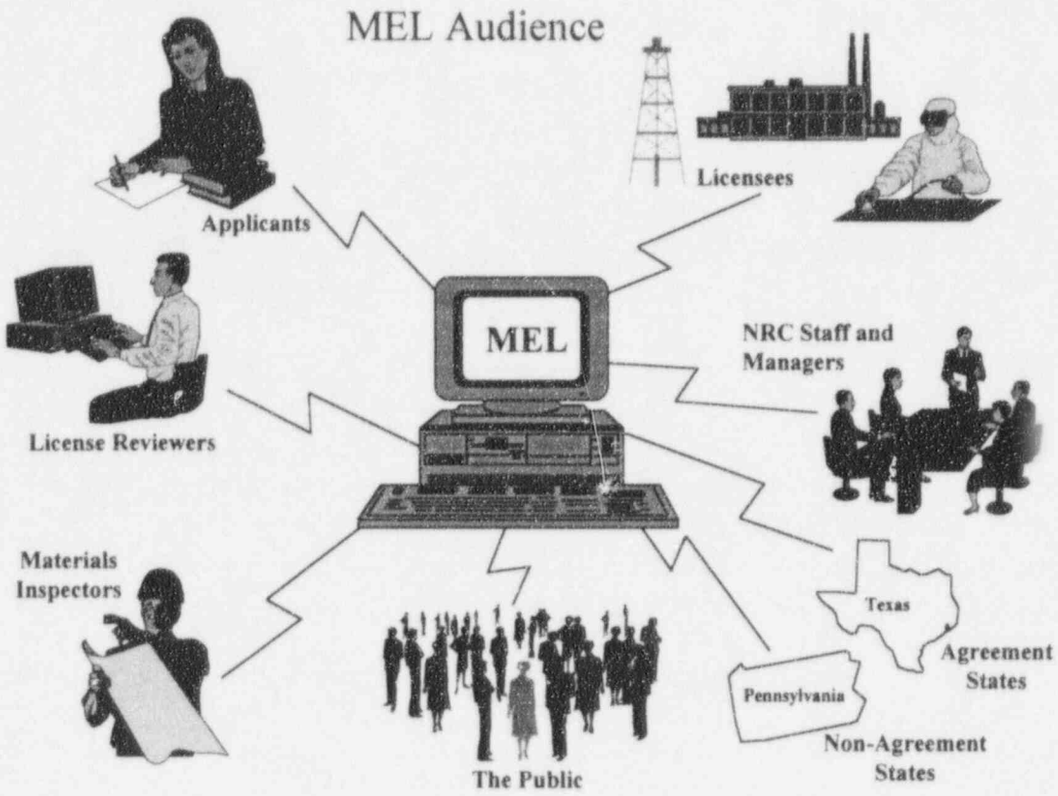

Figure 1.3 Potential Users of MEL. *Diverse users will be able to simultaneously access the information contained within MEL from multiple geographic locations.*

1.5 Principles of Development

The principles underlying the early conceptual design of MEL were that it be modular, structured, reusable, and accessible:

- Modular in that MEL will be constructed in units that will be easy to build, manage, and maintain;
- Structured in that the content will be organized in a specific framework to enhance usability;
- Reusable in that certain units, sections, or paragraphs can be written once and used many times; and
- Accessible in that MEL will be able to be reached by many means, including electronic media (e.g., CD-ROM, diskette), INTERNET, and, for NRC materials licensing and inspection staff, through the NRC wide area network. Although MEL resides in an electronic format, the staff recognizes the need to provide up-to-date guidance in paper copy, as well, to those who request it.

1.6 Scope

The remainder of this report is organized as follows:

- Section 2 describes the approach the team used to create MEL.
- Section 3 provides a detailed description of MEL.
- Section 4 provides a users' view of MEL.
- Section 5 requests comments, including recommendations, and suggestions.

2 Structured Approach for Creating MEL

2.1 Overview

This section describes the approach that the team used to develop MEL. A cross-functional team composed of NRC staff selected from the entire agency created MEL. To the maximum extent possible, the team performed activities in parallel (e.g., writing, editing), rather than following NRC's more traditional sequential approach. In addition, the MEL team used information technology (e.g., groupware) to enable online collaborative and simultaneous writing, reviewing, and editing. This use of information technology allowed team members to work remotely so that the team did not have to be co-located for most of its work.

The approach also included use of the storyboard mechanism in which an end product is visualized as a whole before it is created. A storyboard is a form of extended outline that—

- details the contents of each section of the document to be written,
- describes how the author should write each section,
- describes the graphical presentations to be used in each section, and
- provides information needed to create each section efficiently and in coordination with other sections.

Two types of review teams, technical reviews (Pink Team) and management reviews (Red Team), have been used in developing MEL. A third type of team, a publishing review (Gold Team), will be used in the future.

2.2 Steps in Creating MEL

The MEL prototype was created using the steps described in the rest of this section.

2.2.1 Consolidating and Cataloging Existing Information

In its first major task, the team consolidated and cataloged information currently used in the licensing process and created a high-level conceptual outline. NRC regulatory guides, standard review plans (SRPs), NUREG-series reports, policy and guidance directives (P&GDs), responses to Technical Assistance Requests, American National Standard Institute (ANSI) standards, International Atomic Energy Agency (IAEA) documents, and other Federal and international standards were categorized and cross-indexed into a high-

level conceptual outline (see Figure 2.1). Information was assessed and conceptually indexed into the following categories of text:

- Good as is
- Modify
- Update
- Discard and rewrite

Once indexed, significant amounts of the text were converted into an electronic format.

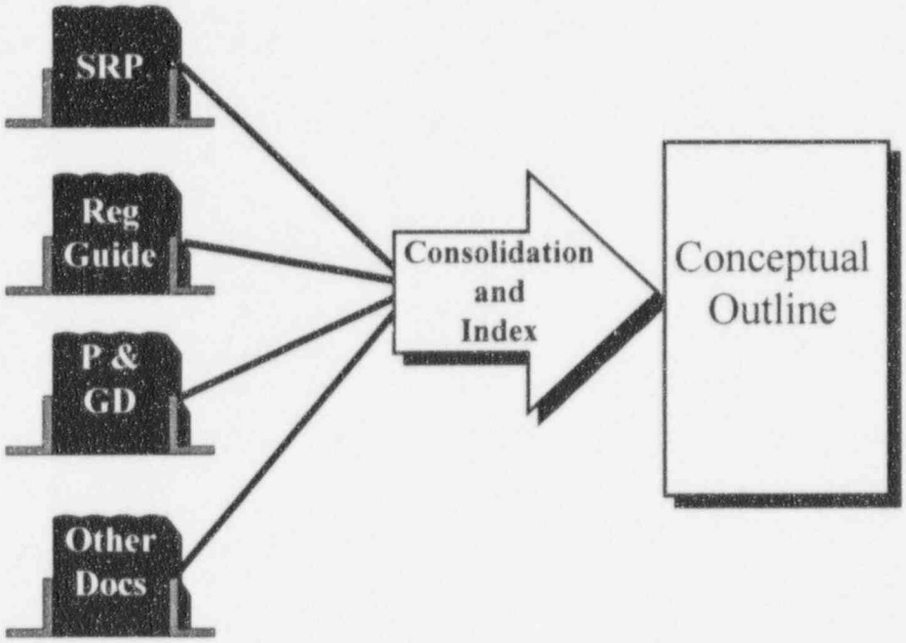

Figure 2.1 Consolidating and Cataloging the Vast Array of Existing Guidance. *The team consolidated and indexed information currently used in the licensing process.*

2.2.2 Developing the Outline

In order to achieve the objectives established for MEL, for example, ease of use and flexibility (Section 1.3), the MEL team decided to shift the organization of materials licensing guidance **from a system organized by program type (i.e., the purposes for which radioactive material is used) to a topic-based scheme.**

The team started with a representative cross section of regulatory guides and SRPs used in the current licensing process, ensuring that these documents covered a wide variety of uses of both sealed and unsealed materials. The team separated the contents of these documents into administrative and regulatory topics, noting the associated concepts and

issues. The team recognized that existing documents did not address certain topics (e.g., public dose) and that new text would need to be developed.

Next, the team rearranged all of the administrative and regulatory topics with their associated concepts and issues together with ideas for additional features of MEL into an outline.

The goals of the outline were to—

- address issues only once,
- provide all information at the time guidance is needed, and
- supply cross references to other applicable materials.

An overview of the outline is shown in Figure 2.2. Additional information is presented in Section 3.

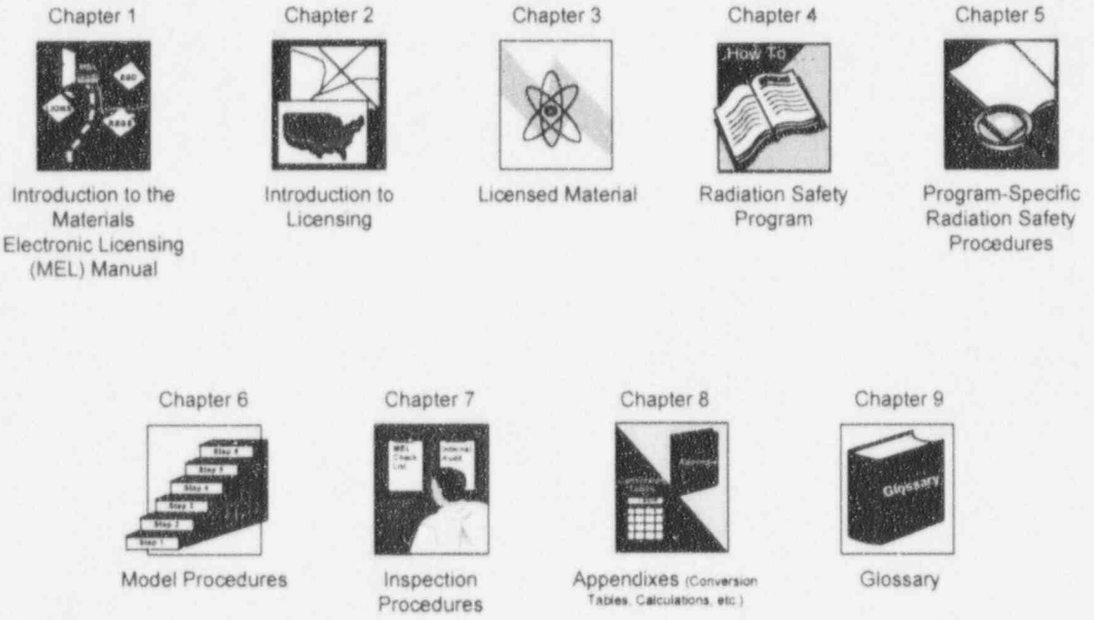

Figure 2.2 Overview of Outline for MEL. *This graphic depicts the number and title of chapters in MEL.*

2.2.3 Storyboarding Selected Outline Sections

The MEL team consolidated the outline into logically related units, allowing significant sections to be merged. The remaining items in the outline were then subdivided into segments requiring a detailed outline or storyboard of the contents of each section. Each storyboard provided a general section theme, specific section theme, specific notes to the author on issues to address, references and specific regulations to consult, and ideas for graphics, tables, lists, and so forth. Storyboarding provided a methodology to ensure that

all appropriate information was transferred from the old sections of the program-specific guidance to the new topical format. Storyboarding also allowed the team to ensure that pertinent information from all of the catalogued documents (Section 2.2.1) is included in MEL.

2.2.4 Writing

The MEL team wrote text and worked collaboratively to resolve comments received as a result of various reviews. Rather than making specific writing assignments, the MEL team members chose the topics on which they wrote, used the references identified in the storyboards to draft text, and covered the matters identified in the storyboards. The goal was NOT to address every conceivable issue or variation of an issue, but rather to provide sufficient information on the assigned topic to address most of the issues and their most common variations (what the team called the "75% solution"). The team plans to address the remaining "25%" in program-specific guidance in Chapter 5 of MEL.

The use of groupware was important to the writing process for the following reasons. Groupware allowed team members to remain at their regular duty stations while writing online (see Figure 2.3).

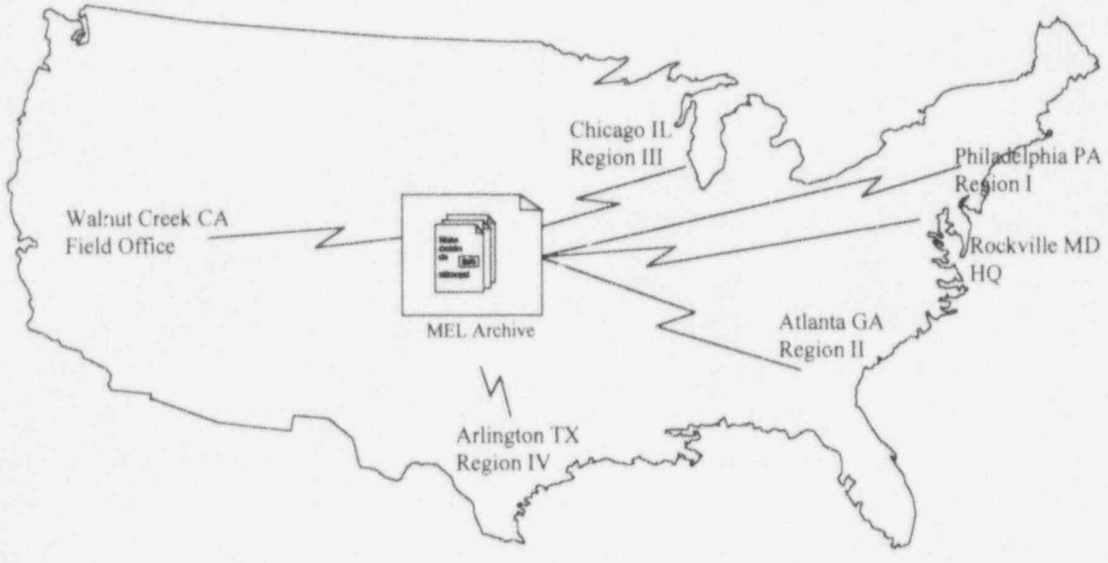

Figure 2.3 Use of Groupware in Writing MEL. *Groupware allowed team members to remain at their regular duty stations while writing online.*

The topics were "self-contained," allowing the team members to work simultaneously without awaiting input from another team member. The team was able to monitor progress, ensure version control, obtain status reports, and exchange additional guidance

online with one another throughout the writing and editing process. A professional editor and a team member suggested changes online to ensure readability and clarity.

2.2.5 Reviewing MEL

The MEL process requires scheduled technical and management reviews by the following groups: Technical Review (Pink) Team, Management Review (Red) Team, Publishing Quality Assurance (Gold) Team and the public, including Agreement and non-Agreement States. Each group has specific responsibilities in the operation, governance, and design of MEL.

A Pink Team (technical review) team consists of five or six individuals (i.e., key managers and/or highly technical staff members) charged with giving technical and policy guidance to the MEL team. A Pink Team gives guidance to the team on early adjustments to the concept, outline, storyboards, and early writing of products to ensure that effort is not wasted when the later extended writing of these products begins.

A Red Team is a management review team that reviews a document late in the development process. It normally meets for the first time to review the writing after two-thirds of the time allotted for detailed writing has occurred. If required, a Red Team may conduct a review of the completed product. The Red Team may also review a document after public comments have been received and responded to, and before the guidance is finalized for use by applicants, licensees, and the NRC staff and managers. The purpose of the Red Team is to provide parallel management and technical review of, and concurrence with, the product.

A final type of publishing quality assurance review (Gold Team) is conducted by appropriate staff. The Gold Team performs its review before a product is released to ensure that printed copies are accurate and of high quality.

The teams review the outline, storyboards, the text, and the graphics. As a result of each review, the developing electronic library is refined to enhance its completeness and accuracy and to ensure that it remains true to its user friendly concept.

For this report, Pink and Red Teams reviewed the concept and outline. Pink Teams reviewed the storyboards, the text, and the graphics. A representative from Illinois, an Agreement State, participated in the Pink Team storyboard review.

3 Description of MEL

3.1 Introduction

As shown in Figure 2.2, MEL is divided into chapters. These chapters are briefly described in the rest of this Section 3.1.

Chapter 1 describes the structure of MEL, how to use it, and what views are available.

Chapter 2 provides an introduction to licensing, explaining such matters as NRC's legislative authority, the types of materials NRC regulates, the Agreement State program, and other administrative matters of interest to applicants and the NRC staff. In addition, the basic information now found in Items 1 to 4 of NRC Form 313, "Application for Material License," are explained. Note that the discussion of the identity of the applicant will also address the related issue of change of control or change of ownership.

Chapter 3 discusses the information now found in Items 5 and 6 of NRC Form 313, that is, radioactive material, chemical/physical form, possession limits, and proposed uses of radioactive material. This chapter also addresses NRC's requirements for financial assurance for decommissioning (e.g., 10 CFR 30.35), emergency plans (e.g., 10 CFR 30.32(i)) and environmental assessments. These issues are addressed in Chapter 3 because applicants often modify their initial requests to alleviate the need to comply with these NRC requirements, for example, a reduction in requested quantities of material so that financial assurance is not required. With respect to sealed sources, Chapter 3 will describe the NRC's and Agreement States' procedures for evaluating the acceptability of sealed sources and devices for licensing purposes.

Chapter 4 discusses, generically, 16 topics that are applicable to most radiation safety programs at licensees' facilities. These topics are listed in Table 3.1.

Table 3.1 Topics Applicable to Radiation Safety Programs at Materials Licensee Facilities.

Management	Facility	Dosimetry	Maintenance and Inspection
Radiation Safety Committee	Termination of Activities	Public Dose	Transportation
Radiation Safety Officer	Radiation Detection Instruments	Handling Procedures	Emergency and Abnormal Event Procedures
Personnel Involved in Licensed Program	Material Receipt and Accountability	Surveys	Waste Disposal

Chapter 5 contains information specific to various types of uses, for example, radiography, well logging, medical. The portion of Chapter 5 devoted to radiography will contain the special requirements in 10 CFR Part 34, the portion dealing with well logging will contain the special requirements of 10 CFR Part 39, while the portion devoted to medical applicants will contain the special requirements in 10 CFR Part 35.

Chapter 6 will contain model procedures (e.g., package opening, emergency) that applicants may use "as is" or as a basis for developing procedures tailored to their unique situations.

Chapter 7 will provide access to the field notes NRC inspectors use in conducting inspections. Applicants and licensees may find these notes useful in conducting the annual review of their radiation protection programs as required by 10 CFR 20.1101(c).

Chapter 8 will include various appendixes including interactive tables and unit conversions (e.g., curie units to Becquerel).

Chapter 9 will include a list of abbreviations and a glossary.

This new structure of NRC policy and guidance by topic within MEL will help to keep guidance documents up to date, develop new guidance documents quickly, and improve the consistency of policy for different uses of radioactive material. General information on each subject will exist in only one location, ensuring that all documents will include the same information on the particular subject. Any changes to that information will be immediately reflected in all documents that draw from the central repository. Guidance on uses of source material, special nuclear material (SNM), and byproduct material in sealed sources will be similar to the guidance that pertains to use of unsealed byproduct

of material. New documents can be developed rapidly since the general information on each subject will already be written, approved, and ready to use thus leaving only policy specific to the new document to be developed.

3.2 "Write Once—Use Many Times" Concept

As a first step toward creating MEL, the team compiled the information that would apply to various uses of unsealed byproduct material. Although the information was selected as applicable to uses of unsealed byproduct material, most of the information can be applied more broadly. Thus, when the team begins to collect the information pertinent to sealed sources containing byproduct material, it will use, as a base, the text for unsealed byproduct material. Obviously some subjects, such as internal dosimetry, will not be pertinent to sealed material. Other subjects, however, will be used with little or no change, such as sections on management and external dosimetry. The team will then augment these sections with text on leak testing, sealed-source inventories, and other topics that would not be found in the information on use of unsealed byproduct material. Similarly, the team anticipates creating sections on the use of source material and on the use of SNM by building on text previously written for sections on use of sealed and unsealed byproduct material (see Figure 3.1).

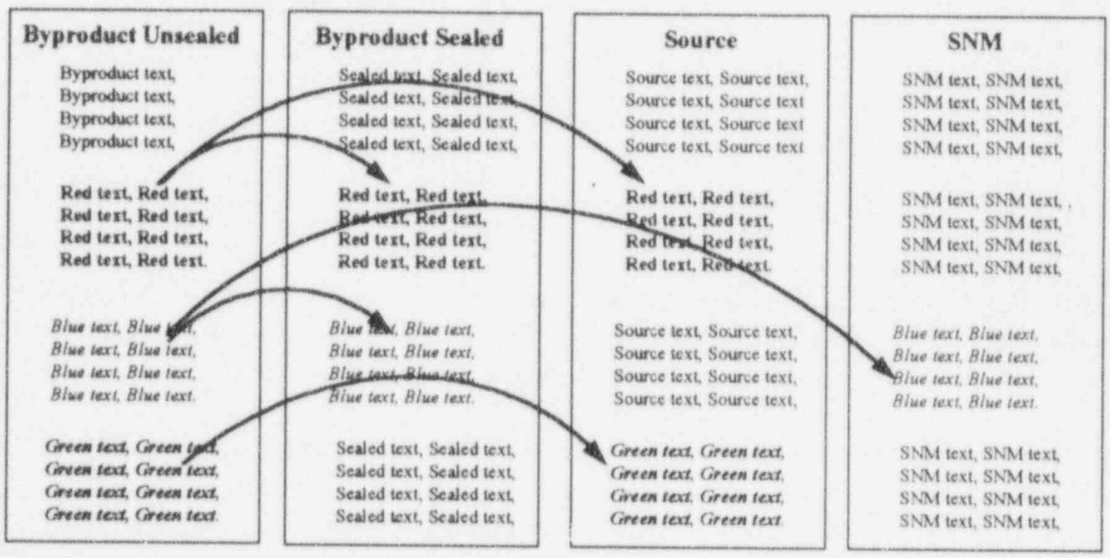

Figure 3.1 Write Once—Use Many Times. *This is a conceptual model showing text for byproduct material—unsealed being used as a basis for creating generic radiation safety information pertinent to byproduct—sealed, source, and special nuclear materials.*

Information extracted from the section on unsealed byproduct material, is intended to be used to create program-specific guidance documents in the same conceptual way that it will be used to create the repositories for source, special nuclear, and sealed byproduct materials. For certain topics, the information contained in Chapter 4 of MEL for unsealed byproduct material will contain exactly what is needed as guidance for the specific use. In other cases, however, there may be more material in Chapter 4 than is necessary for a

byproduct material will contain exactly what is needed as guidance for the specific use. In other cases, however, there may be more material in Chapter 4 than is necessary for a particular use, or additional material may be needed to address specifics of the use being discussed (see Figure 3.2).

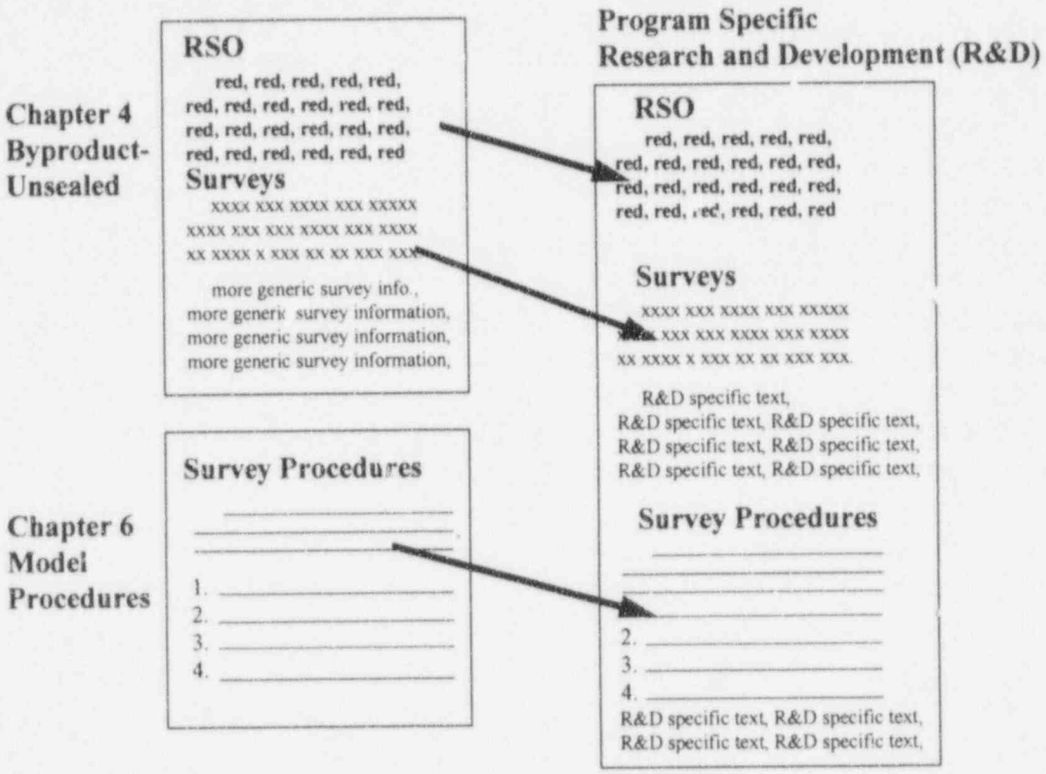

Figure 3.2 Developing Program-Specific Guides. *This conceptual model showing the use of generically applicable information as a basis for creating program-specific guidance. This is a second example of the "write once—use many times" concept.*

MEL is also intended to be used to create guidance documents on individual topics. For example, a guide on health-physics surveys could be created by extracting survey information from the sealed and unsealed byproduct material sections and from the source and special nuclear material sections.

In the past, NRC's regulatory guides did not reflect recent policy decisions and had to wait for the next revision of a regulatory guide to be included. Since the documents were paper-based, changes required that the text be reset and reprinted. Since MEL exists as an electronic library, NRC policy decisions can be immediately incorporated into MEL. Documents that extract information from the affected section would thereby be changed immediately, ensuring that both electronic and paper versions of guidance are up to date.

3.3 Flexibility of MEL

The structure of MEL expands easily to incorporate new uses of material and new topics. By incorporating pre-existing text into new guidance documents, the team anticipates much faster development of guides. The majority of the text needed for a guidance document for a new use of licensed material will already exist in the general sections of MEL. Only that guidance specific to the new use needs to be developed and approved.

The structure of MEL also allows policy for specific uses to be generalized. For example, very few laboratories using SNM possess sufficient material for criticality to be an issue. The guidance concerning criticality issues will, therefore, be included only in the guide specific to these types of laboratories. If, however, new uses arise for which criticality is an issue, the policy found in the guidance documents for laboratories using critical mass quantities of SNM could serve as a basis for development of more general policies applying to all users of these quantities.

3.4 Graded Approach in the Licensing Process

The team plans to take a graded approach in the licensing process when it develops the program-specific information in Chapter 5 of MEL. By graded approach, the team means obtaining different amounts and types of information, depending on the types and quantities of radioactive material authorized, the qualifications related to radiation safety of personnel, and the inherent safety features of the radioactive materials and devices requested for licensure.

The team is considering the best way of determining the minimal amount of information to be submitted by an applicant, recognizing that the minimal information (1) may differ among categories of licensees and (2) must be sufficient to make the findings required by the Atomic Energy Act of 1954, as amended, and the applicable provisions of 10 CFR Parts 30, 40, and 70.

Much of the text in Chapter 4 is informational and may not necessarily reflect the extent of information that NRC may ultimately determine is appropriate for different categories of licenses (i.e., the text of Chapter 5 of MEL).

For example, applicants requesting authorization to use a gas chromatography (GC) source, portable gauge, or fixed gauge, items that are relatively safe, may be expected to provide a very limited amount of information on a given subject or meet easily reached "standards" (e.g., Radiation Safety Officer (RSO) may need little if any training and experience in addition to that expected of authorized users). The potential uses of these types of licensed materials may be inherently limited and the devices may incorporate engineered safety features. In light of these considerations, applicants may not need to provide detailed information in support of an application. In addition, the program-specific guidance for these categories of licenses (in Chapter 5 of MEL) may allow

interested users of the electronic version of MEL to be linked to the appropriate section of Chapter 4 of MEL to obtain additional background information on the topic (e.g., RSO qualifications, duties).

Some categories of licensed activities are inherently more hazardous than others; for example, individuals involved in radiographic work and in sterilization of products at pool irradiators have been killed or experienced serious radiation-induced injuries. In license categories such as these, it may be appropriate for applicants to meet more rigid and prescriptive "standards" and to provide more detailed information, allowing them only limited flexibility to change their programs.

Applicants for more safety significant types and quantities of radioactive material (e.g., Type A license of broad scope) will be expected to provide a different level of detail on a topic (e.g., RSO of a broad scope license will need extensive training and experience commensurate with the types and quantities of licensed material authorized by the NRC license). Licensees in this group may be expected to provide the criteria its Radiation Safety Committee will use to approve users, rather than provide documentation of the training and experience of each user.

In Section 5.4 the team requests readers' suggestions and recommendations on the best approach to determining the minimal information to be submitted by applicants for various categories of licenses.

3.5 Setting the Performance-Prescriptive Indicator

Before developing the Chapter 5 program-specific guidance, the team is considering the degree to which NRC should move to a more performance-based approach to licensing that might allow licensees more flexibility in managing their programs without having to amend their licenses before implementing certain changes. This would be in contrast to NRC's current more prescriptive approach that requires prior NRC approval before making many types of changes in a radiation safety program.

Given the current regulations, the team would be interested in readers' views on which categories of licenses are appropriate for a more performance-based approach. Suggestions are also welcome on how to move toward the performance-based approach, assuming the following: (1) no change in the regulations and (2) appropriate changes in the regulations (identify the assumed changes). See Section 5.4 for specific issues on which the NRC seeks comments.

4 The User's View of MEL

4.1 How Guidance is Provided Today

Today if an applicant calls NRC and asks for information on how to get a license (e.g., to use byproduct material for R&D, including use in laboratory animals), he receives Regulatory Guide 10.7 (Rev. 1) dated August 1979, accompanied by an errata sheet dated July 1984, "Application for Material License" (NRC Form 313), and current copies of NRC's regulations in 10 CFR Parts 19, 20, 30, 170, and 171. Depending on discussion, NRC staff may also forward Regulatory Guide 10.8 (Rev. 2), dated August 1987, with a recommendation that the applicant review the model procedures originally developed for medical licensees and use them as a basis for creating procedures for his R&D work. The applicant then must review these documents, identify what must be submitted in support of the application, try to identify the current regulatory references because those in the Regulatory Guides refer to "old" 10 CFR Part 20, not the current version that became effective January 1994, and finally prepare his submission to NRC.

4.2 How Paper Copies of Guidance Will Be Provided

After MEL is implemented, an applicant requesting a paper copy of the same guidance as discussed in Section 4.1 would receive a single, concise, up-to-date document that may look very much like today's regulatory guides. However, it would differ in that NRC's computer would select from the various chapters of MEL the specific information applicable to an R&D applicant and then print out the one document containing current appropriate guidance. If one thought of the contents of MEL as paragraphs in bins (corresponding to the MEL chapters) numbered 1 through 9, then the guidance document for R&D applicants might be created by collating paragraphs in the table below:

Table 4.1 How Paper Copies of Guidance *Might* be Collated

TOPIC	DESCRIPTION	SOURCE OF PAGES
MISCELLANEOUS	Administrative information (e.g., where and how to file)	Bin 2, paragraphs 1, 2 and 3
NRC FORM 313, #1	Type of Application	Bin 2, paragraph 15
NRC FORM 313, #2	Name, Mailing Address	Bin 2, paragraph 17
NRC FORM 313, #3	Address where licensed material will be used or possessed	Bin 2, paragraphs 19 and 20
NRC FORM 313, #4	Contact name and phone no.	Bin 2, paragraph 21

Table 4.1 How Paper Copies of Guidance *Might* be Collated (continued)

TOPIC	DESCRIPTION	SOURCE OF PAGES
NRC FORM 313, #5	Radioactive material (radionuclide, chemical or physical form, possession limit)	Bin 3, paragraphs 12, 14, and 17
NRC FORM 313, #6	Purposes for licensed material will be used	Bin 3, paragraph 21
NRC FORM 313, #7	Individuals responsible for radiation safety (RSO)	Bin 4, paragraphs 33, 34, and 36
NRC FORM 313, #8	Training for individuals working in or frequenting restricted areas	Bin 4, paragraphs 66, 67, and 71; Bin 5, paragraph 12 for information specific to training those who handle research animals; Bin 6, paragraphs 52 and 53 for a model training program
NRC FORM 313, #9	Facilities and equipment	Bin 4, paragraphs 93-97, 115-20; Bin 5, paragraphs 82-85 for information specific to animal research facilities
NRC FORM 313, #10	Radiation safety program	Bin 4, paragraphs 145-150; Bin 5, paragraphs 93, 101, and 156 for information specific to animal research programs; Bin 6, paragraphs 72 and 79 for model procedures for package ordering, opening and receipt and for emergencies; Bin 7, paragraphs 66-68 for NRC field notes for inspections of R&D licensees
NRC FORM 313, #11	Waste management	Bin 4, paragraphs 200, 202, and 205
NRC FORM 313, #12	License fees	Bin 2, paragraph 14
NRC FORM 313, #13	Signature	Bin 2, paragraph 1

Let's now take a closer look at the paragraphs selected for preparing the response to Item 10 of the current NRC Form 313. Bin 4 (or Chapter 4 of MEL) addresses 16 topics that are generically applicable to most radiation safety programs; some of these (e.g., waste management) are called out as separate items on NRC Form 313. Of the remaining 16 subtopics, an R&D applicant will receive at least some material taken out of Bin 4 on

dosimetry, public dose, handling procedures, surveys, maintenance and inspection, material receipt and accountability, transportation, management involvement and audit programs. No information would be selected from the subtopic, radiation safety committee (RSC), since it usually is not applicable to R&D programs, see figure 4.1. Note that certain model procedures would be provided and that NRC field notes for R&D inspections would be included to assist the applicant in setting up an audit program.

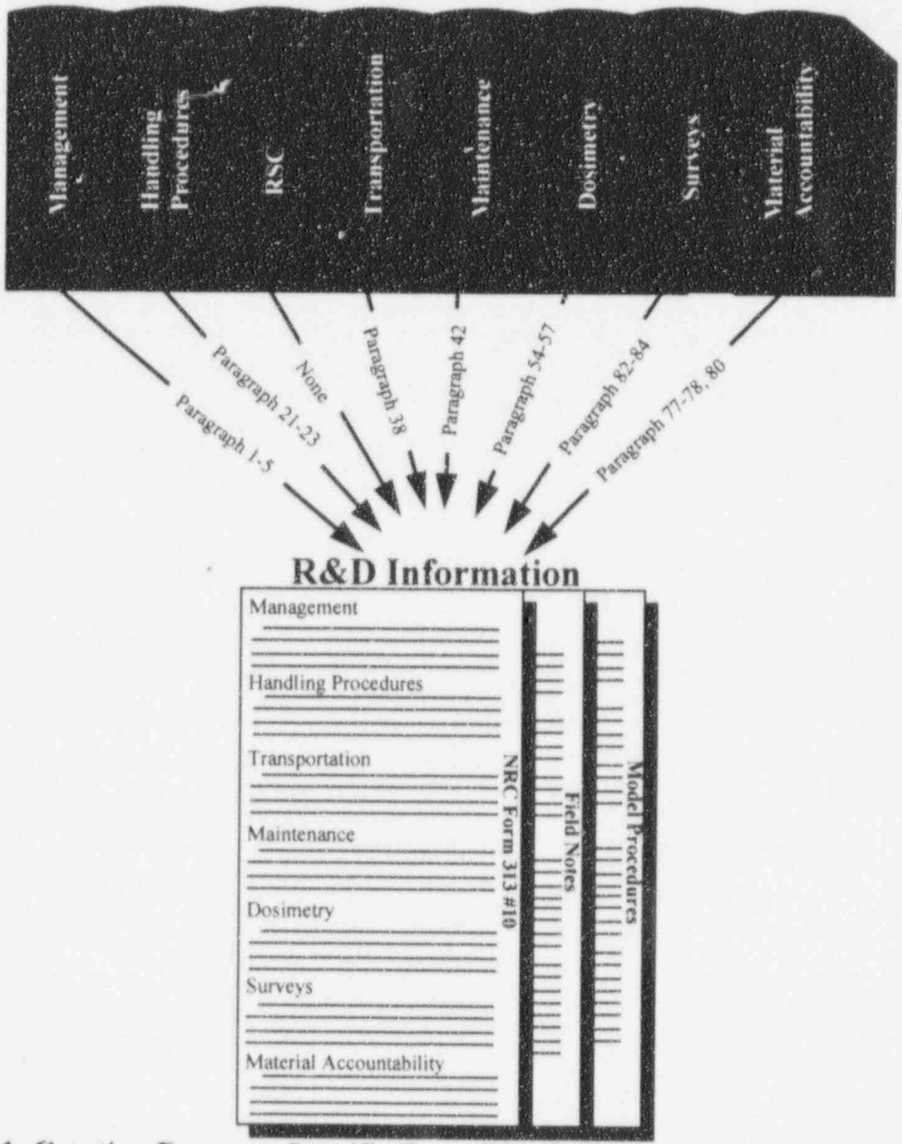

Figure 4.1 Creating Program-Specific Text. *This figure depicts the selection of text appropriate to R&D applications.*

4.3 How Electronic Copies of Guidance Will Be Provided

For those applicants with computer capabilities, NRC is planning to provide electronic versions (e.g., via electronic mail, CD-ROM, diskettes, and the INTERNET) of the paper

documents described above. The MEL team expects that these electronic versions could have the following features, although exact mechanisms have not yet been determined:

- Certain text (identified on a computer monitor screen as bold, green, italics) will be "linked," allowing the user (1) to see the actual text of regulations mentioned in a guidance document, (2) to be reminded of the meaning of abbreviations and acronyms, and (3) to refer to other documents discussed in the guidance document.

- Additional information can be obtained on topics or subtopics (e.g., if only a small amount of information is ordinarily provided to R&D applicants about RSOs, an applicant may obtain additional information (from Chapter 4 of MEL) about NRC's position on appropriate duties and responsibilities of RSOs by simply "pointing and clicking").

- Certain calculations (e.g., radioactive decay, shielding), unit conversions (e.g., curie units to Becquerels), and interactive tables will be available to use either while preparing a license application or during the performance of licensed activities. (Using an interactive table, a user could, for example, enter a radionuclide and find the appropriate values of A_1 and A_2 for transportation-related decisions or enter radionuclides and requested possession limits to determine whether financial assurance for decommissioning is required).

- Other databases (e.g., all or pertinent parts of the sealed source and device registry database) will be "linked," accessible, and searchable.

4.4 Advantages of Implementing MEL

The advantages of the new way of conducting business after implementing MEL are as follows:

- Information will exist in one place where it will be easy to keep up to date.

- All information pertinent to a given category of use will be so maintained that it can be collated easily into a single, concise document without the need to reference other documents and to attempt modifying them to fit a particular category of use.

- Additional explanatory material on many topics or subtopics will be available for those who need it (and, for those needing paper copies, request it).

- Applicants and licensees will have access to and use the same information that is provided to NRC staff and managers so that there is "no hidden agenda." Applicants and licensees will know the guidance that the staff is expected to follow in reviewing an application, and will be able to see the reviewers' notes of critical information needs and questions.

5 Request for Comments

5.1 Introduction

On the basis of the previous discussions of MEL, the NRC staff is seeking comments on the structure of MEL, how to engage interested individuals and groups outside of NRC during this rapid development of regulatory policy, certain aspects of the development of program-specific guidance in Chapter 5 of MEL, and potential implementation issues that may arise from this proposed way of developing future NRC guidance. Specific questions follow in Sections 5.2 through 5.5.

Because of the magnitude of this undertaking, the MEL team believes that it was appropriate to move quickly to solicit comments from all interested parties. During the comment period on this document, the staff is actively seeking comments (both positive and negative).

5.2 Structure of MEL

- The team reorganized guidance from a programmatic to a topical basis. Using the general outline of MEL as described in Section 3:
  - identify any major technical topics that were not addressed.
  - if there are topics that you believe NRC should not address, please identify them and explain your rationale.
- Readers who have experience using a variety of NRC documents on materials licensing issues are invited to--
  - identify and provide a description of documents, ideas, concepts, formats, and so forth, that worked well for them in the past and that the NRC staff should try to incorporate into MEL.
  - provide similar information about documents, ideas, concepts, and so forth, that did NOT work well and that the staff should avoid.
  - provide ideas, concepts, formats, and so forth, from non-NRC documents.

MEL relies on the "write once—use many times" concept in several ways.

- Section 3.2 and Figure 3.2 describe conceptually how Chapter 4 text in MEL on byproduct material—unsealed will be used as a basis for creating text for byproduct material—sealed, source material, and special nuclear material. Using this information,

  – provide suggestions and recommendations for refining or improving the concept.

- Section 3.2 and Figure 3.3 describe conceptually how generically applicable text will be used as a basis for creating text for program-specific guidance in Chapter 5 of MEL. Using this information,

  – provide suggestions and recommendations for refining or improving the concept.

As explained in section 4.2, when MEL is implemented, the team expects to be able to provide guidance **routinely** in paper and electronic copies (e.g., electronic mail, INTERNET, CD-ROM, and diskettes).

– Identify the preferred option for **routine** receipt of guidance.

– Provide suggestions for other methods of **routinely** receiving the guidance.

When the MEL team has program-specific guidance available for one or more categories of licenses, the team will be especially interested in comments from affected licensees. The team is considering the best way to present program-specific guidance for **review and comment** and has identified the following as possible options:

✓ Present the entire text of the program-specific guidance without differentiating between generically applicable text and new program-specific text (as far as content is concerned, this option would be similar to a draft regulatory guide)

✓ Present the entire text of the program-specific guidance with some differentiation (e.g., font type, size) between generically applicable text and new program-specific text

✓ Present only the new program-specific text

✓ Present the new program-specific text with "pointers" or other indicators identifying the source of generically specific text

- Based on the explanation in Section 3.2,

- identify the preferred option for **review and comment**.

- provide suggestions for other methods of presenting the text for ease of **review and comment**.

5.3 How to Engage Interested Individuals and Groups Outside of NRC During Rapid Development of Regulatory Guidance

Section 2.1 describes the cross-functional nature of the teams that created the MEL concept, design, and text to date and performed the reviews. The NRC staff is looking for ways to involve interested individuals and organizations (e.g., recognized technical experts, Agreement States, non-Agreement States, other governmental agencies, professional societies) in actively assisting during the rapid development of MEL.

- Recognizing certain legal constraints (e.g., conflict of interest),

  - provide suggestions and recommendations for expanding the involvement of non-NRC staff during the development of MEL.

- Explain how NRC can expeditiously reach interested parties and obtain their comments as quickly as possible to consider while developing MEL.

- Section 2.3.4 discusses the team's use of groupware to facilitate development of MEL.

  - Provide comments, suggestions, and recommendations for ways in which information technology could be used to allow interested individuals and organizations to participate in the development of MEL.

The NRC staff would welcome comments from professional societies, standard-setting organizations, or other similar groups that may be interested in developing model programs to submit to NRC for possible inclusion in the program-specific guidance in Chapter 5 or Chapter 6 of MEL.

5.4 Certain Aspects of the Development of Program-Specific Guidance in Chapter 5

- Section 3.4 describes the "graded approach to licensing" concept.
  - Provide suggestions and recommendations on the best approach to determining the minimal information to be submitted by applicants for various categories of licenses.
- Section 3.5 discusses the team's consideration of a move to a more performance-based approach to licensing.
  - Are there now categories of licenses for which a performance-based approach is NOT appropriate (that is, a prescriptive approach is appropriate)? If so, identify them.
  - Identify categories of licenses that lend themselves to the performance-based approach.
  - If a more performance-based approach is appropriate and desirable, provide suggestions and recommendations on how to achieve that goal using two assumptions: (1) no change in the regulations and (2) appropriate changes in the regulations (identify the assumed changes). If there are other assumptions please state them.

5.5 Implementation

MEL is in the early stages of its development and the staff has not focused its attention on the detailed issue of implementation.

- On the basis of past experience, the NRC expects to develop program-specific guidance for a given category of licensees and use it for review of applications for new licenses, amendments, and renewal requests. The guidance would not be applied to existing licensees who had not sought to amend or renew their licenses.
  - If NRC proceeds in this way with the new MEL approach, what problems may occur in implementation? What barriers do you see? Please provide potential solutions.
  - Provide suggestions or recommendations for other methods of implementation.

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)
NUREG-1541
Draft

2. TITLE AND SUBTITLE
Process and Design for Consolidating and Updating Materials Licensing Guidance

Draft Report for Comment

3. DATE REPORT PUBLISHED
MONTH: April
YEAR: 1996

4. FIN OR GRANT NUMBER

5. AUTHOR(S)
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6. TYPE OF REPORT
Draft

7. PERIOD COVERED (Inclusive Dates)

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)
Office of Nuclear Material Safety and Safeguards
Division of Industrial and Medical Nuclear Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)
Same as 8. above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This report describes the concept and approach for developing the Materials Electronic Library (MEL). The Business Process Redesign team for the licensing of materials conceived, as an integral part of its vision for the redesign of this licensing process, the idea for MEL. To establish MEL, the NRC will consolidate and update numerous regulations and policy and guidance documents supporting the materials licensing process into a single, comprehensive electronic repository for use by the NRC, Agreement and non-Agreement States, licensees, applicants, and the public.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)
Materials Electronic Library, MEL, materials licensing, guidance, consolidation, updating

13. AVAILABILITY STATEMENT
Unlimited

14. SECURITY CLASSIFICATION
(This Page)
Unclassified
(This Report)
Unclassified

15. NUMBER OF PAGES

16. PRICE

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