LABAT-ANDERSON INCORPORATED
2200 CLARENDON BOULEVARD, SUITE 900, ARLINGTON, VIRGINIA 22201 (703) 525-9400
FAX: (703) 525-7975 TELEX NUMBER 5106005227 LABAT AND

July 3, 1991

Ms. Elizabeth Shelburne
U.S. Nuclear Regulatory Commission
Office of the Licensing Support
System Administrator
Mail Stop EW-W571
Washington, D.C. 20555

Reference: Task Order No. 2, April 17, 1991

Subject: Deliverables for Items f and g of Task Order No. 2 under Contract No. NRC-40-90-346

Enclosures: One draft add-on paper on alternative approaches to compliance evaluation and four draft Step 2 materials

Dear Ms. Shelburne,

Please find enclosed the deliverables required for Items f and g of the above-referenced task order. Under Item f, there is a consolidated Draft Step 2 Add-On document addressing alternative approaches to compliance evaluation for the three processes of documentary material identification, preparation, and submission. Item g deliverables include four draft Step 2 materials, one each for documentary material identification, preparation, and submission, and one for compliance assistance and reporting. This submission is in accordance with your direction to proceed with these deliverables on June 27, 1991.

These draft deliverables complete our obligation under Items f and g of the above referenced task order. If you have any questions, please do not hesitate to call me at (703) 525-9400.

Sincerely,

LABAT-ANDERSON Incorporated

Tony Neville
Project Manager

cc: Shirley Crampton
LAI Contract file (8629-004)
Enclosures

Draft Step 2 Add-on Paper:

Alternative Approaches for Compliance Evaluation

Licensing Support System Administrator's

Quality Management Plans

for

Task Area 7 of Contract No. NRC-40-90-346

Task Order No. 2

July 3, 1991

by

LABAT-ANDERSON Incorporated

with

Price Waterhouse

DRAFT STEP 2 ADD-ON: PAPER ON ALTERNATIVE APPROACHES FOR COMPLIANCE EVALUATION

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Acronyms Used in Draft Step 2 Add-on Paper

ASCII	American Standard Code for Information Interchange
CAR	Compliance Assistance and Reporting
CE	Compliance Evaluation
Commission	Nuclear Regulatory Commission
DLO	Designated LSS Official
DMI	Documentary Material Identification
DMP	Documentary Material Preparation
DMS	Documentary Material Submission
DOE	Department of Energy
HLB	Hearing Licensing Board
HLW	High Level Waste
LSS	Licensing Support System
LSSA	Licensing Support System Administrator
LSSARP	Licensing Support System Advisory Review Panel
NRC	Nuclear Regulatory Commission
OLSSA	Office of the Licensing Support System
O&M	Operations and Maintenance
PALB	Pre-licensing Application Licensing Board
PDLS	Priority Document Loading Schedule
QA	Quality Assurance
QC	Quality Control
QMP	Quality Management Plan

DRAFT STEP 2 ADD-ON: PAPER ON ALTERNATIVE APPROACHES FOR COMPLIANCE EVALUATION

July 3, 1991

1.0 Executive Summary

The selected alternative approach for compliance evaluation recommends evaluating the results or outputs from each of the three LSS processes at a single point - the point at which processed materials are submitted to the LSSA. The LSSA O&M and CE contractor's roles in this proposed approach is to work together to compile and analyze process outputs and report their findings to the LSSA. Grades are assessed on each batch of processed material reviewed and LSS Participants are notified concerning "failed" batches (those not meeting LSSA-prescribed standards) requiring rework and resubmission. LSS Participants are also notified of the types of errors detected in all batches, thus permitting LSS Participant error correction and feedback, and improvement of their processing operations. In the DMI process, materials determined to be non-relevant do not get submitted. These materials are evaluated on-site by the LSSA CE contractor.

Evaluating the effectiveness of procedures and LSS Participant adherence to their compliance plans (process evaluations) requires on-site auditing. Therefore, process evaluations are only conducted periodically and as needed when output results indicate unsatisfactory or inconsistent performance. More extensive process evaluations are conducted, together with LSSA-provided LSS Participant assistance, during the initial phase of LSS Participant processing (project startup). Extensive evaluations particularly pertain to DMP processing and cases where significant volumes of backlog material must be processed. Since more errors are likely to be committed when a new process begins. Early monitoring can improve and stabilize processing, resulting in increased LSS database quality and decreased auditing. error correction, and rework costs.

The recommended alternative approach was arrived at through separate analysis of each of the LSS processes (Documentary Materials Identification, Preparation, and Submission). Issues of compliance evaluation were identified and analyzed for each of the LSS processes (Section 3.0 - Determining What to Evaluate: Issues of Compliance Evaluation). These issues were analyzed in the context of each LSS process separately (Sections 4.1 - Documentary Material Identification, 4.2 - Documentary Material Preparation, and 4.3 - Documentary Material Submission). Recommendations within each section reflect *what* should be evaluated in assessing LSS Participant compliance for the respective process. Based on those analyses, two alternative approaches to overall compliance evaluation implementation were identified and analyzed (Section 5.0). The recommendation in Section 5.0 determined *how* compliance evaluation should be performed. The recommended alternative approach to compliance evaluation evolved by combining the recommendations in Sections 4 and 5 (Section 6.0 - Recommended Alternative Approach).

2.0 Introduction

This deliverable was developed under Item f, Section I.A.1 of Task Order No. 2 under Contract No. NRC-40-90-346 as a single, integrated draft of the three deliverables required under Item f. It identifies and analyzes alternative approaches to the Licensing Support System ("LSS") Administrator's ("LSSA") fulfillment of his obligations in evaluating the compliance of parties and potential parties ("LSS Participants") participating in the Department of Energy's ("DOE") license application for the establishing of a geological high-level waste repository according to the Nuclear Regulatory Commission's ("Commission") Rules of Practice ("the Rule") as stated in 10 CFR Part 2. The Statement of Work requires that:

> "The contractor shall identify, analyze, and document alternative approaches that might be implemented to establish an effective compliance evaluation program and the pros and cons of each approach, taking into account the degree of effectiveness, the burdens on the LSS Participants and the costs to the LSSA. The contractor's recommended approach shall include supporting rationale for that choice."

This paper specifically addresses compliance evaluation as it relates to the LSS Participant requirements for identifying (Documentary Materials Identification, or "DMI"), preparing (Documentary Materials Preparation, or "DMP"), and submitting (Documentary Materials Submission, or "DMS") backlog and contemporaneously generated documentary material relevant to the licensing proceeding. (DMI, DMP, and DMS are hereinafter collectively referred to as the LSS processes).

Identifying and analyzing alternative approaches to LSS Participant compliance evaluation requires determining *what* should be evaluated within the scope of LSS processing. There are issues that pertain to all of the LSS processes which must be resolved. First, the *focus* of evaluation (process outputs, processing procedures, or both) must be determined. Second, the volume of material to be evaluated and the frequency of conducting evaluations must be determined. Third, grading mechanisms, which may trigger specific consequences to LSS Participants relative to their levels of performance, must be incorporated into an evaluation approach. These issues must be analyzed in the context of each LSS process, as the unique dynamics of each process influence evaluation considerations differently. After performing this analysis, alternative implementation methodologies for evaluating compliance can be identified and analyzed (i.e., *how* compliance evaluation should be performed). The conclusion of these analyses is a single recommendation for compliance evaluation that includes: identifying the aspects of each LSS process that will be evaluated; how they will be evaluated; and the implementation methodology for evaluating compliance.

The following assumptions were used when developing the draft Step 2 Add-On document:

- The analyses and recommendations assume certain roles for the LSSA O&M and CE contractors. The O&M contractor role would include receiving submitted materials from LSS Participants, performing data validation and quality checks, and providing processing results data to the LSSA and CE contractor. The CE contractor role would include performing process evaluations, processed data auditing, and reviewing data on process results provided by the O&M contractor and the LSS Participants.

- Guidance and standards will be formulated later as part of the development of the Big Book reference materials for LSS Participants. References or examples of possible LSSA guidance or standards are used as illustrations.

2.1 Criteria and Basis for Analysis

The evaluation criteria referred to in the Statement of Work will be utilized throughout the various stages of analysis described. The criteria are: 1) the degree of effectiveness of the approach to evaluate compliance; 2) potential burdens the approach may place on LSS Participants; and 3) the costs to the LSSA of utilizing the approach.

It is important to define and understand the "effectiveness" criteria in order to apply it appropriately and consistently. "Effectiveness" in this context pertains to the ability of the approach to allow the LSSA to achieve its responsibilities under the Rule regarding LSS Participant compliance evaluation. There are two specific sets of LSSA responsibilities relevant to compliance evaluation. One set of responsibilities are more clearly specified and defined under the Rule and pertain to ensuring that LSS Participants identify, prepare, and submit, in a timely manner, all relevant documentary materials to the LSS (10 CFR Part 2, sections 2.1003-2.1006, 2.1009, and 2.1011). The purposes for ensuring timely production of materials are to minimize delay in the high-level waste licensing process and to ensure a thorough safety review based on all relevant information as defined by the Rule. The other relevant responsibility is referred to in section 2.1011(d)(7), which states:

> "The LSS Administrator shall be responsible for the management and administration of the Licensing Support System, including the responsibility to...ensure LSS availability and *the integrity of the LSS database* (emphasis supplied)."

The Rule does not elaborate on the meaning or intent of "integrity of the LSS database." However, in a database context, "integrity" typically refers to the accuracy of data residing on the database and its impact on retrievability, i.e., that the data on the database reflect precisely the information contained in the documentary material represented.

Meeting the former set of responsibilities involves evaluating LSS Participant *performance*, i.e., determining if LSS Participants are producing the appropriate materials and if production is on schedule. The latter set of responsibilities requires evaluating LSS Participant processing and *data quality*, i.e., determining if materials are being processed correctly and determining to what degree the data produced by LSS Participants accurately represents the documentary material being processed. Different techniques and approaches are utilized to evaluate general performance versus data quality. Therefore, different conclusions related to compliance evaluation approaches will be reached when focusing on evaluating general performance as opposed to focusing on evaluating data quality. Specifically, different conclusions may be reached regarding what gets evaluated, where in the process it is reviewed, and how much material is audited. Likewise, the burdens on LSS Participants and costs to LSSA will vary according to the LSSA responsibilities achieved. Determining the "effectiveness" of an approach therefore depends on the degree of emphasis placed on achieving one set of responsibilities or goals as opposed to the other. This paper attempts to balance both sets of goals in the analysis.

3.0 Determining What to Evaluate: Issues of Compliance Evaluation

Compliance evaluation program issues were identified to organize a paper on alternative approaches. Each issue fit into one of three discrete areas. To facilitate analysis and discussion, the issues involved with compliance evaluation were grouped into these three categories. The issue groupings are: 1) determining the focus of evaluation (processing procedures and adherence to compliance plans or the results of the process); 2) determining the volume of material to be audited (and, thereby, determining the frequency of auditing or review); and 3) developing an evaluation or grading mechanism with consequences regarding rework, error correction and revisions to the process used, and the degree of LSSA oversight.

3.1 Compliance Evaluation Issue 1: Determining the focus of evaluation - the process or the results

Compliance can be evaluated by examining processing procedures and the LSS Participant's adherence to those procedures, by reviewing only the results of the processing, or some combination of both. Different measurement schemes may be appropriate, depending upon the overall objectives of the compliance evaluation program. An approach that emphasizes measuring the results of the process, i.e., the quantity and quality of the output, does not require focusing on the process used for achieving that output. On the other hand, an approach that focuses on measuring the process, i.e., the quality and effectiveness of processing procedures and how well the LSS Participant is following them, does not necessarily measure the quality of the output data. The latter approach assumes that as long as the data is processed according to procedure, the data will be accurate. Evaluating both the process and the process results may be the approach which is most cost effective.

3.2 Compliance Evaluation Issue 2: Determining the volume of material to be evaluated

In determining the volume of material to be audited by the LSSA and how frequently audits are to be performed, the cost of auditing must be balanced with the cost of reprocessing data of unacceptable quality (rework), should auditing reveal serious processing deficiencies. With more frequent audits, the potential volume of material to be reworked is smaller. Frequent, close scrutiny of processing and process output may achieve higher quality processing and output, particularly if feedback is provided to LSS Participants often. With less frequent audits, the volume of material evaluated is greater, but the cost of auditing is significantly reduced. There is also a greater risk that unacceptable data may bypass quality review, thereby reducing the quality and effectiveness of the LSS database.

Assuming that checking for errors will be accomplished by using statistical sampling techniques, the size of the sample must be determined for a specified accuracy rating. The sample size will be dependant upon both the size of the batch of processed material being audited and the level of accuracy required. Where audit checks are performed must also be determined. Such determinations will affect recommendations concerning the volume of material to be audited and the frequency of audits. This issue is especially important for DMI and DMP, where recommendations must made be regarding the auditing of:

- Material determined relevant and material determined non-relevant, or only material deemed relevant that passes on to preparation
- DMP processes, i.e., indexing, scanning, and ASCII conversion, or only of completely processed records to be submitted.

Production processing, such as DMI, DMP, and DMS, typically improves after project startup, when processing stabilizes. Process stabilization is the point when processing achieves production quality and pre-established output goals on a consistent basis. Constant, intense monitoring and supervisory involvement are normally utilized during the project startup phase to achieve stabilization, after which the level of monitoring and supervision are substantially reduced. The volume of material to be audited may therefore vary, depending on the LSS Participant processing phase. Material submitted after the first six months of processing may require less checking than material produced and submitted during the first six months.

3.3 Compliance Evaluation Issue 3: Developing an evaluation (grading) mechanism with consequences regarding rework, corrections, and the degree of LSSA oversight.

The grading mechanism must be designed so that proper DMI, DMP, and DMS practices are

encouraged, inefficient and error-producing procedures and techniques are identified and revised, and objectives of the entire process are met. The grading mechanism must specify and clearly communicate how a grade is determined and what constitutes acceptable and unacceptable levels of quality ("passing" and "failing"). LSS Participants can then effectively achieve and maintain a compliant processing status. Procedures must be developed for grade notification to LSS Participants and rework activities. Guidelines for different types and quantities of errors must be developed that will determine an appropriate degree of LSSA oversight of LSS Participant activities and the imposition of penalties when necessary. Grading and errors identified must be tracked in evaluating LSS Participants' performance. This area of consideration also examines the potential role of the LSSA O&M contractor in compiling information on submitted data quality and correcting certain errors versus the LSS Participants' performance of all error-correction activities.

The development of a strategy for penalty imposition is not formulated in this paper. However, the issue regarding the imposition of penalties and the types of penalties to impose arises in all LSS processes. In addition to rework and closer LSSA oversight, a series of warnings issued by the LSSA is the most reasonable and recommended approach to assessing penalties, even though such warnings may be ignored. Warnings should be issued for performance problems to 1) prompt action, or 2) ensure database integrity, with penalties imposed for serious, deliberate, or repeated offenses. The penalty should be denial of access to the LSS. In addition, if the LSS Participant does not show good faith effort and will not reach substantial compliance, party status should not be granted or, if already granted, revoked. Once the LSS is on-line and available for LSS Participant usage, and assuming that the LSS Participants come to depend on it, revocation of access rights may become a powerful means of ensuring future compliance. Since the LSSA exists, in part, to assist LSS Participants in becoming and remaining compliant and thus achieving party status, a recommendation of denial of party status is a loss for both the LSS Participant and the LSSA. Thus, the revocation of access rights should be a last resort.

4.0 Alternative Approaches Analysis for the LSS Processes

The compliance evaluation issues are analyzed in the context of each LSS process (DMI, DMP, and DMS) below.

4.1 Documentary Material Identification (DMI)

Compliance Evaluation Issue 1: Determining the focus of evaluation - the process or the results

Any discussion of alternative compliance evaluation approaches for DMI must recognize that DMI is composed of several distinct elements. Unlike DMP and DMS where process results include all documentary material originally received for processing, DMI processing sends forward only relevant material for further processing. Documents determined to be non-

relevant, and therefore not appropriate for submission to the LSS, do not leave LSS Participant sites. This difference may dictate a different approach than the approaches used for DMP and DMS.

Evaluating the results only

Under this approach, documents identified as relevant or non-relevant (DMI process results) by the LSS Participants would be evaluated for compliance with the DMI guidance. Backlog materials determined to be non-relevant by a LSS Participant would be evaluated at the LSS Participant's location by the CE contractor. The LSS Participant must segregate this material, or track it in such a way that it could be recreated for audit purposes. As part of the compliance process, LSS Participants would be required to maintain records indicating the reasons why particular documents were determined not relevant to the DMI guidance. Documents determined relevant by the LSS Participants would be reviewed either at the LSS Participant's site and before further processing, or at the point of submission to the LSS.

Evaluation of the results will indicate the correct or incorrect application of DMI guidance to the screening of materials. The responsibility of the LSSA would be to review these results. This approach places a burden on the LSS Participants to maintain the integrity of non-relevant batches of material and records, and requires the LSSA to use contractors to visit the LSS Participants' sites. This approach ensures the integrity and completeness of the material in the LSS. Once the backlog is processed, periodic audits of contemporaneous documentary material screening procedures would be required.

Evaluating the process only

Under this approach, the design and execution of procedures for determining the universe of documents to be screened, the LSS Participants' guidance and procedures for determining relevance of the materials screened, and the LSS Participants logging and control (tracking) procedures would be examined for their effectiveness. Evaluating the DMI process would involve evaluating whether the LSS Participants compliance plan and operating procedures accurately guided the DMI process.

Evaluations would focus on the following areas:

- design and execution of the procedures used to determine the universe of documents to be screened for relevance and the universe of documents compiled based upon those procedures

- design and execution of the procedures used to determine relevancy of material screened based on the Regulatory Guide for Topical Guidelines and DMI Guidance

- design and execution of the tracking mechanisms used by the LSS Participant to ensure batch integrity and document reasons for relevancy determinations

- design and execution of the procedures used to determine relevancy of contemporaneously generated materials

This type of review cannot be performed by evaluating the results only and must be performed on-site by the LSSA compliance evaluation (CE) contractor. Included could be a review of the process that determines where and how backlog materials are selected for screening, ensuring that adequate consideration is given to obtaining all potentially relevant materials for LSS inclusion. This approach would represent a thorough review which may result in accurate relevancy determinations on the part of the LSS Participant, based on detailed feedback to the LSS Participant. However, once a LSS Participant's performance has been determined to be "on track," further DMI process evaluation may be required only on an occasional basis, or may be useful only as problems surface in a review of process results which indicate problems.

Initial evaluation of the DMI process at the LSS Participant's location would determine whether the LSS Participant was following their LSSA-approved compliance plan. A benefit of this approach is that it yields a thorough analysis of how well LSS Participants are selecting materials and adhering to their plans, procedures, and production schedule. It may reduce recordkeeping burdens on LSS Participants as compared to a results-oriented evaluation approach. However, this approach does not directly ensure achieving a key objective of the DMI process, that only relevant and appropriate material is entered into the LSS. Due to the somewhat subjective nature of relevancy screening, even the best formulated and implemented procedures will not guarantee appropriate results. Thus, evaluating only the process would not give satisfactory information about the end product.

The cost of this approach is high for the LSSA due to the requirement of longer, and possibly more frequent on-site visits by the LSSA CE contractor.

Recommendation on Focus of Evaluation

Based on this analysis, it is recommended that a two-tiered approach be taken. The first tier includes reviewing materials determined to be relevant, which should occur at the point of submission of the material to the LSS. The second tier involves auditing materials determined not relevant, which must be performed at the LSS Participant's site. This two-tiered approach ensures the correct application of screening guidelines and the completeness of the LSS. Problems with the process would be identified by examining the results of the process. Initial evaluation of the DMI process should be conducted at the LSS Participant's location to determine whether the LSS Participant was following their LSSA-approved compliance plan. The benefit of this approach is that it yields a thorough analysis of how well LSS Participants are selecting materials and adhering to their plans, procedures, and

production schedule.

If evaluation of results points to problems with the DMI process, then subsequent process evaluations would be appropriate. Once a LSS Participant demonstrates the ability to accurately make relevancy determinations and maintain adequate records concerning relevancy determinations, process examinations could be significantly reduced unless the end-result examinations reveal other problems.

The LSSA O&M contractor will evaluate the relevant document determinations at the point of their receipt for loading into the LSS. The LSSA CE contractor will evaluate the non-relevant document determinations at the contractor's site, and examine the process as necessary, based on their analysis of process results.

DMI Compliance Evaluation

Issue 1: What should be the *focus* of evaluation?

Alternatives	Advantages	Disadvantages
Results: • Relevant material submitted to the LSSA • Non-relevant material retained at the LSS participant site	• Indicates correctness of DMI Guidance application • Ensures integrity and completeness of LSS material • Can be performed without visiting LSS participant site (for relevant material)	• Cannot determine level of plan/procedures adherence • Cannot determine if potentially relevant universe of material was properly selected
Processes	• Indicates correctness of DMI Guidance application • Yields more thorough analysis of LSS participant's adherence to plans and procedures	• Requires on-site evaluation (less cost effective) • Does not yield satisfactory information about integrity and completeness of LSS material
***Recommendation:* Evaluate results as primary basis for evaluation; evaluate process at startup and when results are unsatisfactory	• Includes all advantages of evaluating results and processes • Permits cost effective relevant and non-relevant material evaluation	• May allow inaccurate decisions and faulty procedures to go undetected after initial phase, but reduces risk

Compliance Evaluation Issue 2: Determining the volume of material to be evaluated

Appropriate volume to be audited

As stated above, the DMI process is unique in that both non-relevant material and relevant material must be audited in order to ensure the completeness, relevance, and fitness for purpose of materials submitted to the LSS. While it would be ideal to require that the LSS contain only relevant documentary material, due to the subjective judgements the LSS Participants must make, it is inevitable that non-relevant material will be entered into the LSS. Establishment of an appropriate auditing volume and frequency is one means to minimize the amount of non-relevant material included and maximize the inclusion of relevant material.

The volume of material to be audited should depend upon the compliance history of the individual LSS Participant. For example, if a LSS Participant is consistently compliant, the frequency of auditing could be decreased for that LSS Participant. Although this would mean a larger volume of material subject to each evaluation, the risk of more extensive rework is a reasonable one to take. A LSS Participant whose relevancy determinations prove to be unreliable should be audited more frequently. The volume of materials accumulated at each audit would be smaller, and a larger percentage of the material would be reviewed. This approach leads to the conclusion that, upon initiation of the LSS process, all LSS Participants should be audited frequently, perhaps monthly, until enough experience with the individual LSS Participants' performance is obtained to have a reasonable basis to apportion the compliance evaluation priorities.

Recommendation on Volume of Material

It is recommended for the DMI process that the volume/frequency of compliance evaluation be tied to the LSS Participant's current level of performance. By tying the type of evaluation to performance, the cost to the LSSA is reduced to a minimum level and the burden on the LSS Participants is increased only if they are not fulfilling their DMI responsibilities. This provides incentive for the LSSA to furnish adequate guidance in the DMI area and for the LSS Participant to effectively implement it.

Issue 2: How often should material be reviewed; how much material should be reviewed?

Alternatives	Advantages	Disadvantages
• Frequently (smaller amounts of material evaluated more often)	• Provides closer scrutiny of subjective decisions for relevancy to ensure consistency in screening	• More review of more material may unnecessarily increase costs of evaluation
• Periodically (larger amounts of material evaluated less often)	• Permits review of results and performance with lower cost than more frequent review	• May allow inaccurate decisions and faulty procedures to go on undetected; costs of rework may be higher
***Recommendation:* Frequently at first, then tie to LSS participant performance thereafter	• Permits early detection of non-compliance and faulty procedures • Provides evaluation when and where needed; more cost effective	• May allow inaccurate decisions and faulty procedures to go undetected after initial phase, but reduces risk

Compliance Evaluation Issue 3: Developing an evaluation (grading) mechanism with consequences regarding rework, corrections, and the degree of LSSA oversight.

Options

There are five options identified for grading and notifying LSS Participants of passed or failed batches. They are:

- "Passing" grade with notification to LSS Participants of errors to correct
- "Passing" grade with no notification to LSS Participants (leaving the responsibility to find and correct errors with the LSS Participant)
- "Passing" grade with no notification to LSS Participants (leaving the obligation to correct errors with the LSSA)
- "Failing" grade with opportunity to correct (rework) and readdress potential problems with process execution
- "Failing" grade with automatic LSSA/Commission implementation of sanctions in addition to rework

Notification of errors, whether they are corrected by the LSSA or not, is a key piece of feedback for the LSS Participants. Without this feedback, they will not know where problems are beginning to surface. Therefore, all "no notification" alternatives are eliminated. In addition, a "failing" grade with automatic sanctions is not appropriate because it is inconsistent with the goals of the LSSA in assisting the LSS Participants with compliance.

It may appear to be reasonable for the LSSA to correct errors detected in batches that "pass" (i.e., where the margin of error is acceptable). However, LSSA error correction may require making decisions out of context. LSS Participants may have had facts available affecting their decision that are not readily available to the LSSA at the time of error detection. Requiring LSSA consultation with LSS Participants to correct every uncovered error would create an onerous procedure. This leaves, as the better option, notifying LSS Participants of errors, for "passing" or "failing" grades, where LSS Participants are responsible for correcting the errors. Since relevancy decisions are subjective, LSS Participants may disagree with quality assurance decisions. In such cases, a procedure is needed to facilitate resolution of disputes.

Recommendation on Grading

It is recommended for the DMI process that the grading of LSS Participant compliance reflect both notification to LSS Participants of inaccurate relevancy determinations for batches that pass and similar notification for batches that fail, withthe additional requirement that failed batches be re-examined to eliminate deficiencies.

Issue 3: What should be the grading procedure?

"Passing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Notify LSS Participants of errors to correct	LSS Participants receive feedback for improvement; error correction activity is facilitated	Error correction may be delayed if errors are detected by LSSA but correction activity is left to LSS Participant
No notification; LSS Participants find and correct errors	Error correction responsibility is properly left with LSS Participant; LSSA is "relieved" of error correction duties	No feedback is provided to LSS Participants
No notification; LSSA corrects errors	Error correction is executed immediately after detection by LSSA	No feedback is provided to LSS Participants; LSSA may not be able to make corrections

"Failing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Correct (rework) and readdress potential problems with process execution with no immediate penalty	Allows LSS Participants reasonable opportunity to improve; facilitates LSSA achievement of LSS Participant and LSS objectives	Continuous rework may simply become part of LSS Participant processing, with no further incentive to improve
Correct (rework) with immediate imposition of sanctions	Provides more direct incentive to remain in compliance	Does not consider elements of "rule of reason" or consideration of "good faith" effort

DMI Compliance Evaluation Recommendation Summary

Key Processes	Process/Results	Volume/Frequency	Grading
• Select documents for screening • Screen for relevancy	• Evaluate results (relevant and non-relevant decisions) as primary basis for evaluation • Evaluate process when results indicate problems • Evaluate processes at startup to ensure compliance and effectiveness of procedures • Evaluate process periodically after startup	Results: • Evaluate results (relevant materials) frequently at startup using statistical sampling techniques; thereafter vary by level of LSS participant performance • Evaluate non-relevant material while on-site performing process reviews Process: • Conduct evaluations periodically and when results indicate problems	• Apply grade to relevant and non-relevant batches reviewed • Notify LSS participants of errors (pass or fail) • LSS participants correct errors and rework "failed" batches • Utilize dispute resolution procedure to resolve disagreements over subjective relevancy determinations • Adjust evaluation frequency and oversight based on LSS participant performance • Issue warnings prior to imposing penalties

4.2 Documentary Material Preparation (DMP)

Compliance Evaluation Issue 1: Determining the focus of evaluation - the process or the results

Since the DMP process encompasses the greatest activity of the three LSS processes and therefore requires the most measures, its compliance evaluation will be the most complex. There are many different errors that can be attributed to DMP processing, making it likely that errors will occur during this process.

Results from the DMP process are generated by three main subprocesses:

- indexing header records
- converting images to searchable ASCII text
- scanning and creating electronic images

Each of these processes has various requirements that should be evaluated. For example, header records must be prepared in accordance with coding standards, ASCII text must be retrievable, and images must be linked to a corresponding header record. The focus of the LSSA's compliance assistance and evaluation in DMP is to ensure that process results are accurate, complete, and consistent.

Evaluating the results only

In this approach, all batches submitted to the LSS would be evaluated for compliance with DMP guidance standards. This would involve both electronic and non-electronic submissions.

Areas of measure include the following:

- Proper coding and entry of header records
- Matching of ASCII text to original documents
- Matching of electronic images to original documents
- Timeliness of document preparation, according to compliance plans
- Linkages among header, ASCII and image records.

Compilation and analysis of DMP process results data would provide the LSS with an overall assessment of compliance. Process results for each LSS Participant would indicate whether or not a LSS Participant is performing the DMP processes adequately and indicate problems the LSS Participant is encountering. The LSSA could provide assistance and suggest improvements in these areas where applicable.

Although this approach may not provide enough detail to diagnose the specific problem area, the errors identified will provide clues to be used for further analysis of problems and development of recommendations for preventive actions. The burden on LSS Participants with this approach is minimal, as LSS Participants need only maintain processed batch integrity until after material is submitted, loaded, reviewed, verified, and corrected. Ongoing, systematic review of DMP batched material would constitute the primary costs to LSSA,

which would be less than costs associated with on-site process reviews. This issue is discussed in more detail in Section 5.0 - Approach to Overall Compliance Evaluation Implementation.

Evaluating the process only

In evaluating the process, the procedures involved with the preparation of documents would be audited for effectiveness. For example, process evaluations may focus on the effectiveness of header preparation procedures and the header preparation staff's adherence to procedures.

Evaluating the process forces an analysis of the effectiveness of the process design, the written procedures, and the execution of the process. Instead of reviewing results from accumulated submissions, it involves analyzing:

- Ability of the process to produce accurate headers, ASCII text and images
- Ability of the process to prevent errors from reaching the LSS
- Flow of documentary material throughout the process cycle.

Specific examples of DMP process evaluations may include:

Headers

- Use of authority files
- Accuracy and relevancy of header records
- Adequacy of QA/QC checks for header coding
- Development of header records for all material to be submitted
- Application of LSSA guidelines to the assignment of header records for documentary materials

ASCII text

- Matching of header record to the records for the text
- Accuracy of the OCR process (if applicable)
- Proper use and maintenance of the OCR equipment
- QA/QC checks for ASCII text generation

Images

- Matching of headers to corresponding images and paper originals
- Verification that the compression ratio is as specified in the LSS guidance
- QA/QC checks in the image conversion process
- Use and maintenance of scanning equipment

Evaluating the DMP process would be effective in pinpointing weaknesses in the LSS Participants' systems. It is a very thorough process review which should result in better submissions by the LSS Participants.

The cost of process evaluation includes the time spent by the LSSA and its contractors in analyzing the LSS Participants' processes. LSS Participant burdens include accommodating extensive on-site auditing, which could be potentially disruptive to LSS Participant operations. For situations involving a relatively small number of documents, this could be prohibitively expensive and unnecessary. Where larger document volumes exist, ensuring the effectiveness of the process can potentially prevent a great amount of error, thus saving the cost of rework, which could be significant for this process.

Recommendation on Focus of Evaluation

Examining the results may indicate problems with processes. However, this level of evaluation may not be able to address underlying problems in a LSS Participant's DMP process. To pinpoint the sources of problems it may be necessary to examine DMP processes in depth. A combined approach to compliance evaluation is necessary for the DMP process given the complexity of the header, image, and ASCII code processes and the vital role the DMP process plays in the integrity of the LSS data. This combined approach limits LSSA costs by focusing only on suspected problem areas.

For DMP, compliance evaluation should begin with an examination of the results. If problems are apparent, the focus of evaluation should shift to the DMP processes. For persistent problems, closer and more frequent process audits can be performed. This approach addresses problems at the level at which they manifest themselves and pinpoints problem areas which need to be explored in depth. It avoids unnecessary auditing, thus avoiding extra expense.

The LSS Participant's burden consists of (1) reworking batches of submissions rejected due to unacceptable quality of DMP results and (2) accommodating LSSA CE contractor process evaluations, which may be disruptive to ongoing operations. LSSA's costs related to higher quality LSS Participant output would be lower, and would be higher for those situations where LSS Participants are producing inconsistent or poor quality output.

A variation of this standard may be appropriate for those situations in which large volumes of material are involved. For such cases, the LSSA CE contractor will provide an evaluation team at process startup which will assist the LSS Participant until the process is deemed stable, i.e., producing consistently high quality output at the required rate. Once stability is achieved, this intensified activity will cease and only the results will be monitored. If degradation in the output is noted, further assistance to the LSS Participant could be provided.

DMP Compliance Evaluation

Issue 1: What should be the *focus* of evaluation?

Alternatives	Advantages	Disadvantages
Results: • Header indexing • ASCII text conversion • Image scanning	• Provides overall assessment of DMP compliance • Indicates if DMP processes are being performed correctly • Indicates problem areas	• Insufficient detail provided to diagnose specific (processing) problems
Processes	• Provides analysis of DMP process design, procedures, and execution effectiveness • Pinpoints weaknesses in processes • Potentially prevents errors, reduces rework costs, and yield better submissions	• As a primary focus of evaluation, on-site evaluation may not be cost effective
***Recommendation:* Evaluate results as primary basis for evaluation; evaluate process closely at startup and as needed thereafter	• Includes advantages of evaluating results and processes • Permits cost effective use of evaluation resources	• May allow inaccurate decisions and faulty procedures to go undetected after initial phase, but reduces risk

Compliance Evaluation Issue 2: Determining the volume of material to be evaluated

Appropriate volume to be audited

The impact of DMP processing on the integrity of the LSS database strongly suggests evaluating as much DMP processed material as possible. The alternative that allows for the most comprehensive and frequent evaluation of DMP material will be recommended. Evaluating a DMP batch requires both manual and automated examinations of process results. Therefore, in considering the frequency of evaluations, the difference in efficiencies between manual and automated examinations must be taken into account.

Automated Evaluation

As items are loaded, automated checks can be applied to verify that every image or text record has an associated header record, all mandatory fields in header records are entered, all codes are valid (i.e., they exist on a master file), and the text and image records are readable.

DMP evaluation activities that can be automated include:

- Tracking production volume for headers, ASCII text records and images
- Cross-checking references among headers, ASCII text records and images
- Header field edits (e.g., mandatory fields and valid codes)
- Limited quality checks for text and images.

Automated checking of every batch submitted would be cost effective. The burden would be on LSSA to require the O&M contractor to run special programs that check for every possible error condition and automatically apply a "grade" to the batch. In addition, reports summarizing the results of the automated checks can be reviewed on a periodic basis to detect any negative trends in productivity or quality. The burden would be on the LSSA to have summary reports prepared and executed and to have periodic manual checks performed.

Manual Evaluation

Some checks, such as comparing image and text records with originals, cannot be automated.

Manual DMP evaluation activities include:

- Comparing ASCII text and images to original documents
- Evaluating ASCII text and images for readability and completeness
- Evaluating the quality of subject coding
- Adherence to individual compliance plans and written procedures.

Manual checks are less cost effective since they involve a significant amount of human intervention and are subjective in nature. By this reasoning, periodic audits should concentrate on the measurements that can only be performed manually and not on areas covered by the automated checks used for every batch. This provides a second layer of verification and minimizes the cost to the LSSA.

Recommendation on Volume of Material

Perform all automatic checks on every batch submitted. Periodically conduct audits that concentrate on the checks that must be performed manually. The frequency of the periodic audits can be adjusted according to the grades of every batch checked, so that consistent or significant problems can trigger closer LSS Participant monitoring more quickly. This approach will be comprehensive while proving cost effective. This approach applies to materials that are prepared for both electronic and non-electronic submission.

Issue 2: How often should material be reviewed; how much material should be reviewed?

Alternatives	Advantages	Disadvantages
• Perform automated evaluation of every batch submitted, or of randomly selected batches using statistical sampling techniques to determine batch selection	• Evaluates many critical DMP processes quickly and easily • Permits constant and close evaluation of results in cost effective manner • Accommodates summary reporting of DMP quality by O&M contractor	• Does not allow review of subjective processing (subject indexing and comparing image and text records with original materials) • Requires developing and implementing automated grading programs
• Perform manual evaluation of batches submitted	• Permits comprehensive evaluation of DMP results, including subjective indexing to ensure consistency in subject coding and comparison of images and text to original materials	• Manual review of every batch submitted is expensive • Manual review of fewer batches may allow processing errors (and faulty procedures) to go on undetected; costs of rework may be higher
***Recommendation:* Perform automated evaluation on all batches submitted; conduct manual evaluations periodically, increasing the frequency based on LSS participant performance	• Provides comprehensive evaluation of DMP results cost effectively	• May allow inaccurate decisions and faulty procedures to go undetected after initial phase, but reduces risk

Compliance Evaluation Issue 3: Developing an evaluation (grading) mechanism with consequences regarding rework, corrections, and the degree of LSSA oversight.

Options

The five options identified for grading and notifying LSS Participants of passed or failed batches for DMI (see page 13) apply to DMP.

Grading the results of the DMP process involves specific measures applied to the outputs from each process within DMP. Documents submitted electronically would be reviewed after they have been loaded into the LSS. Documents submitted non-electronically (in hard copy form) could be reviewed for header indexing quality at the point of receipt by the LSSA prior to loading into the LSS. Alternatively, manually-coded headers could be reviewed after they are keyed and loaded and evaluated in the same manner as electronic submissions.

The grading activities applicable to the DMP process would address the following areas:

- Accuracy of header records
- Matching ASCII code to paper documents
- Matching images to paper documents
- LSS Participant verification activities for timeliness and accuracy of corrections
- Integrity of DMP packages (i.e., to assure that they contain documents, appropriate headers, images and ASCII code, all correct and appropriately linked).

Unlike DMI, where evaluation involves only the determination of the accuracy of a relevancy determination, evaluation of DMP is more complex. In DMP, pre-established weighting criteria would be applied to the grade for each DMP process (e.g., header-60%, image-20%, ASCII-20%). Errors would be counted for each element and the weighting criteria would be used to measure compliance within each batch and generate a grade for the batch.

Recommendation on Grading

The recommended approach involves notifying LSS Participants of "passing" or "failing" grades, with indications of the corrections required to be made. If a pattern is apparent, the notification may also include diagnostics to address the problem area. This information would be reported to the LSSA by the O&M contractor at predetermined intervals, i.e., monthly.

This approach is effective because it provides timely feedback to LSS Participants on problem areas and recommended corrections. Continuous quality assurance is important to protect the integrity of the LSS data. By having quality assurance statistics compiled by the O & M contractor, the expense of this process is rolled into the cost of its other duties. A continuous grading process also facilitates the role of the LSSA in evaluating satisfactory

compliance, allowing the LSSA to have relatively current knowledge of LSS Participants' compliance. With regular grading reports, the LSSA has readily available data to indicate the need for site visits by the LSSA CE contractors.

The recommended level of testing will require an extensive O&M/CE staff. Since some header fields are subjective, and therefore difficult to evaluate for correctness, LSS Participants may disagree with quality assurance decisions. A procedure must be established to facilitate resolution of disputes.

Tracking and reporting on a batch basis will yield the most complete information to the LSSA. Although this method requires additional LSSA funding and exchanges with contractors, it does not place any other appreciable burdens on the LSS Participant.

Issue 3: What should be the grading procedure?

"Passing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Notify LSS Participants of errors to correct	LSS Participants receive feedback for improvement; error correction activity is facilitated	Error correction may be delayed if errors are detected by LSSA but correction activity is left to LSS Participant
No notification; LSS Participants find and correct errors	Error correction responsibility is properly left with LSS Participant; LSSA is "relieved" of error correction duties	No feedback is provided to LSS Participants
No notification; LSSA corrects errors	Error correction is executed immediately after detection by LSSA	No feedback is provided to LSS Participants; LSSA has to make corrections

"Failing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Correct (rework) and readdress potential problems with process execution with no immediate penalty	Allows LSS Participants reasonable opportunity to improve; facilitates LSSA achievement of LSS Participant and LSS objectives	Continuous rework may simply become part of LSS Participant processing, with no further incentive to improve
Correct (rework) with immediate imposition of sanctions	Provides more direct incentive to remain in compliance	Does consider elements of "rule of reason" or "good faith" effort

DMP Compliance Evaluation Recommendation Summary

Key Processes	Process/Results	Volume/Frequency	Grading
• Header indexing • ASCII text conversion • Image scanning	• Audit results (prepared records) as primary basis for evaluation • Audit processes at startup to ensure compliance and effectiveness of procedures	Results: • Audit every batch submitted (for automated grading) • Audit batches periodically for subjective content grading and determining accuracy of text/image capture (manual grading) Process: • Conduct audits periodically and when results indicate problems	• Apply automated grading to every batch received • Apply manual grading to batches reviewed periodically for subjective content and comparisons to actual documents for image and text accuracy • Weight subprocess grades to arrive at overall grade for batch • Notify LSS participants of errors (pass or fail) • LSS participants correct errors and rework "failed" batches • Adjust audit frequency and oversight based on LSS participant performance • Issue warnings prior to imposing penalties

4.3 Documentary Material Submission (DMS)

In analyzing the alternatives for DMS, it is important to differentiate between the results of the DMS process itself and the results of the entire documentary material process of all LSS processes. Because DMS is at the end of the processing sequence, errors resulting from identification and preparation can also be found at this time. For purposes of clarity and to avoid redundancy, this section focuses only on measures that directly and exclusively relate to the submission process.

Compliance Evaluation Issue 1: Determining the focus of evaluation - the process or the results

Evaluating the results only

For LSS Participants submitting hardcopy material, specific results of the submission process that are measurable include:

- Number of boxes received in acceptable condition versus total received
- Analysis of total boxes rejected, e.g., missing material, unacceptable physical condition of material, and lost in transit
- Analysis of number of boxes/documents processed or in the backlog (currently in the packing process, currently in transit, and received by LSSA in the last period)
- Number of boxes/documents received in acceptable condition versus goal for substantial compliance relative to the Priority Document Loading Schedule (PDLS) as well as total submissions projected.

For all LSS Participants submitting via electronic media, specific results of the submission process that are measurable include:

- Number of documents/batches accepted versus total submitted
- Analysis of batches rejected due to technical communication problems or other problems with physical submission, e.g., unreadable diskettes, and unacceptable batch sizes
- Number of documents submitted versus goal for substantial compliance relative to the PDLS as well as total submissions projected.

Measuring these results can provide a clear view of the sources of errors in the submission process, since the results directly relate to specific duties in the process. Data collection procedures for these measures can be included within the overall procedures for LSSA O&M and CE contractors.

Evaluating the process only

Evaluating the process, for all LSS Participants, would include such measures as:

- Percentage of material packed or batched correctly on the first attempt
- Amount of material lost or destroyed during the process
- Noted deviation from written procedure
- Rate of throughput versus anticipated rate of throughput

Measuring the submission process can be helpful, but it is not comprehensive. It relies on the ability to detect errors during processing, but common sense indicates that this is not always possible. For example, if a diskette containing a submission batch was damaged in transit, the process might be fine, but the results are unacceptable.

Process measures, in this case, rely on the LSS Participant to provide data about the process. It would be difficult to motivate the LSS Participants to provide this data on a continuing basis, since it involves extra effort and expense on their part. Further, the value of process evaluations for DMS appears minimal.

Recommendation of Focus Evaluation

Evaluate results as the primary basis for examining compliance, and use process evaluations as a supplement.

This approach places the burden for data collection on the LSSA, which must require its contractor to keep statistics regarding document submissions. The LSSA can perform the analysis of the statistics and can then assist the LSS Participants by recommending ways to avoid future recurrence of the errors. Audits would be used, not as a primary method for gathering performance data, but as a supplement to verify LSSA conclusions and gauge LSS Participant "good faith" effort.

DMS Compliance Evaluation

Issue 1: What should be the *focus* of evaluation?

Alternatives	Advantages	Disadvantages
***Recommendation:* Evaluate results: • Hardcopy submissions • Electronic submissions	• Provides clear view of sources of errors • Directly relates to specific process duties and performance	• None
Processes	• Provides information regarding LSS participants' adherence to their DMS procedures	• Not comprehensive • Relies on ability to detect errors during processing, which is not always possible

Compliance Evaluation Issue 2: Determining the volume of material to be evaluated

If evaluations are only performed at six-month intervals, easily correctable problems could go unflagged for that amount of time, which is not reasonable. If evaluations are performed weekly, corrective action can be applied in a timely manner to reduce the overall amount of error and increase throughput.

Because of the technical nature of the electronic submission process, it is reasonable to develop an automated error-flagging mechanism that would allow every batch submitted to be checked. Data readability, for example, is an error that can be detected immediately and forces the rejection of an entire batch. Incorrect batch size is another error that a computerized scan would detect without requiring human intervention. Tracking the number of submissions can be an automated function.

A different situation exists for the submission of non-electronic materials, in that its examination involves a manual process. However, it is still feasible to check every box submitted since the nature of the errors made during submission are very obvious. If a box of materials is submitted improperly, it cannot be accepted into the LSS. For example, if material in a box has been damaged enroute from the submitter, the damage will be visible and the box will be immediately rejected.

For non-electronic submissions, a count must be kept of the number of submissions and the number of rejections. This can be a simple, non-time consuming task that can be done manually for every document or box submitted. Thus the volume of measurement for hardcopy material can be similar to that for electronic submissions.

Process evaluations can be performed on a periodic basis by the LSSA CE contractor.

Any evaluations that can be performed immediately and automatically upon receipt of materials should be applied to all submissions. Process evaluations should be performed for randomly selected batches during periodic audits.

Recommendation on Volume of Material

Evaluate every batch or box of materials submitted. Evaluate the process during periodic audits.
Continuous and frequent measurement of the results of the submission process will allow timely detection of errors and determination of specific corrective action before problems escalate. Process audits can supplement this approach. This provides the LSSA with the most "hands-on" assurance that material is submitted to the LSS properly. This approach places minimum burden on the LSS Participants, but requires the LSSA to use contractors to perform the periodic audits. Evaluating all submissions ensures the integrity of submitted material.

Issue 2: How often should material be reviewed; how much material should be reviewed?

Alternatives	Advantages	Disadvantages
***Recommendation:* Evaluate every batch submitted	• Immediately determines whether material is ready for further processing (hardcopy submissions) or LSS loading (electronic submissions) • Avoids delays from attempting to process "bad" or incomplete data	• Cost required to evaluate every box/batch
• Evaluate submitted materials periodically or at specified intervals	• Avoids cost of evaluating every batch/box submitted	• May permit easily detected errors to go undetected • May permit otherwise avoidable delays due to attempting to process "bad" or incomplete data

Compliance Evaluation Issue 3: Developing an evaluation (grading) mechanism with consequences regarding rework, corrections, and the degree of LSSA oversight.

Options

The five options identified for grading and notifying LSS Participants of passed or failed batches for DMI (see page 13) also apply to DMS.

Grading is very simple in the submission process: either a box or batch is acceptable or it is not. Since the process of submission adds very little value to the material submitted, there will be very little rework involved, other than perhaps repacking a box, reformatting a file, or recreating a packaging index. Batches will be accepted or rejected as a whole.

Since submission is a straightforward process involving little subjectivity, performance problems are indicated by consistent errors, such as an LSS Participant who consistently submits material in boxes that are old or damaged, despite repeated warnings from the LSSA or an LSS Participant who does not ship data diskettes in acid-free envelopes, even after instruction in proper shipping materials. These situations cause a delay in receipt of materials into the LSS and, if occurring consistently, may degrade the LSS Participant's ability to reach substantial compliance.

Recommendation on Grading

Grade LSS Participants on a batch or box level, rejecting submissions that do not meet specified standards. Notify LSS Participants of all errors and require re-submission for failed batches. All errors should be corrected by LSS Participants. When consistent performance problems are noted, issue warnings as necessary and increase process audits accordingly.

Issue 3: What should be the grading procedure?

"Passing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Notify LSS Participants of errors to correct	LSS Participants receive feedback for improvement; error correction activity is facilitated	Error correction may be delayed if errors are detected by LSSA, but correction activity is left to LSS Participant
No notification; LSS Participants find and correct errors	Error correction responsibility properly left with LSS Participant; LSSA is "relieved" of error correction duties	No feedback is provided to LSS Participants
No notification; LSSA corrects errors	Error correction is executed immediately after detection by LSSA	No feedback is provided to LSS Participants; LSSA may not be able to make corrections

"Failing"

Alternatives	Advantages	Disadvantages
***Recommendation:* Correct (rework) and readdress potential problems with process execution with no immediate penalty	Allows LSS Participants reasonable opportunity to improve; facilitates LSSA achievement of LSS Participant and LSS objectives	Continuous rework may simply become part of LSS Participant processing, with no further incentive to improve
Correct (rework) with immediate imposition of sanctions	Provides more direct incentive to remain in compliance	Does not consider elements of "rule of reason" or "good faith" effort

DMS Compliance Evaluation Recommendation Summary

Key Processes	Process/Results	Volume/Frequency	Grading
• Packaging/file formatting • Shipping & transmission	• Audit results (submitted batches/boxes) as primary basis for evaluation • Audit processes at startup to ensure compliance and effectiveness of procedures	Results: • Audit every batch/box submitted Process: • Conduct audits periodically and when results indicate problems	• Apply grade to every batch/box submitted • Notify LSS participants of errors (pass or fail) • LSS participants correct errors and rework "failed" batches • Adjust audit frequency and oversight based on LSS participant performance • Issue warnings prior to imposing penalties

5.0 Alternative Approaches to Overall Compliance Evaluation Implementation

Implementation of compliance evaluation must take into account the combined effect of all individual processes. A key consideration is that the three processes are being performed by many, geographically disparate LSS Participants operating with varying degrees of document processing speed, volume, and sophistication. This concern, along with evaluation volume and frequency issues raise the further question of *how* evaluation should occur. Since the LSSA evaluates all processes and outputs, the most efficient and cost effective way to accomplish compliance evaluation is to review material and data in one place. The alternative is to evaluate process results separately for each LSS Participant at their sites. Analysis of this issue also includes considering the potential roles of LSSA contractors.

Performing all process evaluations after or upon submission

Evaluating results in one place is possible if the review occurs after materials have been submitted. Process evaluations cannot be conducted in one place, as they require an on-site review at LSS Participant sites. However, the burden on the LSSA can be reduced by selecting the alternative of evaluating results first and performing process audits only when the results indicate a potential problem. This approach is consistent with the earlier analysis of each process.

If the review takes place after submission, the LSS searching and reporting capabilities can be utilized. LSS database programs can be utilized to check submitted data for key portions of all phases of processing, including DMI relevancy and DMP results. Therefore, errors detected at this single point can still be identified and traced to the processing point where they occurred. Using the database to identify errors (either during the loading process or after the data has been loaded) is also much less time-consuming, and therefore less costly than manual methods of review. Frequent checks of results can be practically accomplished, thus providing valuable feedback to LSS Participants and the LSSA. Rework, if necessary, can be performed more closely to the point in time when the original batch was created, leading to higher quality processing throughout the term of LSS creation.

Data on submissions would be compiled by the O&M contractor. Results evaluation data can then be reviewed by the CE contractor. Auditing costs are significantly reduced by delaying process measures and only employing them when justified by the process results. This is weighed against the cost of rework, should a serious error be discovered that could have been prevented by an earlier process review. However, this issue can be addressed by integrating process evaluations with a centralized, results-oriented evaluation approach.

Applying this approach to DMI, documents determined to be relevant would be reviewed at the point of submission. However, documents determined non-relevant would be reviewed at LSS Participant sites. For DMP, the evaluations would occur after material has been received by the O&M contractor and may occur before or after material has been loaded. Compilation

of data from DMP process results would primarily be performed by the O&M contractor. Analysis of the data could be performed either by the O&M or CE contractor, and the CE contractor can evaluate the process based on these results as needed.

Except for reviewing non-relevant documents, all process output results could be evaluated centrally, at the point of submission. This approach provides greater flexibility to the LSSA regarding the volume and frequency of audits. The LSSA, through the O&M or CE contractors, can audit every batch submitted for all processes. For situations where LSS Participant performance is consistently high, fewer batches can be reviewed; for those LSS Participants with poor or inconsistent performance, more batches can be reviewed in greater depth. By employing the O&M and CE contractors to compile and analyze submitted data centrally, the LSSA can monitor LSS Participant performance *and* data quality to ensure LSS database integrity.

The burden on LSS Participants would be minimal. Processed material would be submitted to the LSSA and LSS Participants would be notified of quality grading and their error correction responsibilities. No action over and above normal processing, error correction, and process improvement would be required by LSS Participants. Costs to LSSA would involve the development and implementation of a QA program. By centralizing a results-oriented review system, on-site visits can be limited. On-site visits will occur as a result of poor or inconsistent LSS Participant performance, or as part of the implementation of a quality assistance startup program for LSS Participants with large quantities of backlog material to process.

Separate and independent evaluations of each process

The other alternative would be to evaluate each LSS process separately. This approach would require individual process results evaluations being performed by teams of auditors at all of the LSS Participant sites. This places an additional burden and cost on the LSSA due to the obvious cost escalation attributable to the amount of time and travel required by the CE contractor. Performing all evaluations (of both the results and the processes) on-site would be more disruptive to LSS Participant on-site operations.

Additional effort would be required to summarize evaluation input to provide the LSSA with an overview of LSS processing progress. Centralizing evaluation at the point of submission would accomplish this more effectively since the O&M contractor could provide periodic summary reports of batch analysis data to the LSSA, including breakdowns or summaries by LSS Participant. Separate and independent evaluations of each process may offer simpler identification of problems, but offer fewer advantages and are not cost effective. Therefore, this is not a viable alternative.

Combined approach

Overall compliance evaluation implementation must combine elements of both centralized and on-site evaluation in order to provide a comprehensive evaluation program. The effect of such a combined approach for the three LSS processes is summarized in the following table.

Overall Compliance Evaluation Implementation
Recommendation Summary

LSS Process	Activities Performed Centrally Upon or After Submission	How Performed/ By Whom	Activities Performed Independently at Participant Sites	How Performed/ By Whom
DMI	• Measure quality of relevancy determinations for materials submitted; compare results to standards	• O&M contractor performs review based on statistical sampling plan for batches submitted for LSS loading • CE contractor reviews program results • O&M returns "failed" batches to LSS participant for rework; notifies LSS participant of errors for passing and failing batches to improve process • Contractors provide evaluation input to LSSA	• Review materials deemed non-relevant • Conduct process reviews	• CE contractor audits materials deemed non-relevant • CE contractor audits processing procedures and compliance plan adherence • Contractors report evaluation results to LSSA

LSS Process	Activities Performed Centrally Upon or After Submission	How Performed/ By Whom	Activities Performed Independently at Participant Sites	How Performed/ By Whom
DMP	• Measure quality of DMP results (for materials submitted subject to automated review); compare results to standards	• O&M contractor runs automated grading program for batches submitted for LSS loading • CE contractor reviews program results • O&M returns "failed" batches to LSS participant for rework; notifies LSS participant of errors for passing and failing batches to improve process • Contractors provide evaluation input to LSSA	• Manually review DMP results for subjective content and comparison to actual documents • Conduct process reviews	• CE contractor audits processing procedures and compliance plan adherence • Contractors report evaluation results to LSSA

LSS Process	Activities Performed Centrally Upon or After Submission	How Performed/ By Whom	Activities Performed Independently at Participant Sites	How Performed/ By Whom
DMS	• Measure quality of DMS submissions; compare results to standards	• O&M contractor verifies batch/box record count and condition of submission for further processing (manual submissions) or LSS loading (electronic submissions) • CE contractor reviews program results • O&M returns "failed" batches to LSS participant for rework; notifies LSS participant of errors for passing and failing batches to improve process • Contractors provide evaluation input to LSSA	• Conduct process reviews	• CE contractor audits processing procedures and compliance plan adherence • Contractors report evaluation results to LSSA

Conclusions of Issue Analysis

The recommended alternative approach to compliance evaluation must address the issues and recommendations of all of the LSS processes and those of implementation. It must recognize the costs and burdens of the different approaches relative to the benefits gained. The recommended approach will include result and process evaluations and dictate the timing of audits to provide the most useful diagnostic information. The recommended alternative approach to compliance evaluation is discussed below.

6.0 Recommended Alternative Approach

An integrated approach to compliance evaluation is recommended. It incorporates all of the "interim" recommendations under each of the LSS processes, including:

- Focusing on evaluating the results of each process
- Evaluating LSS Participant processes at process startup, and thereafter on a periodic basis as warranted by LSS Participant performance
- Evaluating each batch of material submitted to ensure the integrity of the LSS database, with the option of varying the degree of batch review based on LSS Participant performance
- Notifying LSS Participants of batch quality (grading), requiring LSS Participants to correct errors and rework/resubmit "failed" batches, and adjusting LSSA oversight based on LSS Participant performance
- Adopting the single-point evaluation of results after submission, except for the review of non-relevant material (which will be performed at LSS Participant sites).

The recommended approach contains the following features:

- CE contractor performs an initial audit to ensure that each LSS Participant is in compliance with its compliance plan and is ready to begin processing documents
- O&M contractor compiles results and performs quality assurance on each batch to ensure processing consistency throughout the LSS database building process (based on LSSA input and direction, the O&M contractor can change the frequency of batch review and alter batch size requirements based on LSSA assessment of LSS Participant's performance under DMI, DMP, and DMS)

- O&M contractor reports results to the CE contractor and LSSA and notes any potential problem areas
- O&M contractor notifies LSS Participants of passed/failed batches and errors to correct
- O&M contractor, CE contractor, and LSSA analyze potential problem areas to identify the source
- CE contractor conducts periodic, in-depth evaluations of LSS Participants, including on-site process reviews, as warranted
- LSSA directs further audits to confirm problem areas and provides assistance in correcting them
- LSSA advises the Commission concerning LSS Participant compliance
- LSSA issues or advises the Commission to issue sanctions as required.

In this recommendation, the LSSA will review the LSS Participant compliance plans to ensure that they are complete and adequate to accomplish the intent of the Rule. The CE contractor will visit each LSS Participant during this review and will review the LSS Participant's processes (i.e., DMI, DMP, and DMS) to ensure that all controls are in place and that the LSS Participant is ready to start processing. This initial process check is important to ensure that no serious errors are made initially just because the LSS Participant may be inexperienced or lack understanding of document production techniques. The initial process check can potentially prevent a great amount of error and save the cost of rework for LSS Participants with huge backlogs to process. Additionally, frequent reviews and audits should be conducted during the initial phases of LSS processing (i.e., the first six months). After LSS Participant processing has stabilized, in-depth audits can be limited to every six months (or more frequently for LSS Participants whose processing quality is not acceptable).

The LSSA will not accept any materials for submission until the initial audit has been performed and the CE contractor has confirmed that all procedures are in place and functional. Once the confirmation has been given, LSS Participants will identify, prepare and submit materials in batches.

The batch size (for a submission) and frequency of submission will be determined with input from the LSS Participant, the LSSA, and the O&M and CE contractors. Calculation of batch sizes and frequency of submission will also depend upon the PDLS and the timing of the DOE application.

As materials are submitted, the O&M contractor will perform result measures and quality assurance checks. Initially, smaller batch sizes and frequent result measures will be necessary. As the LSS Participants experience their learning curves, the LSSA can direct the O&M contractor to perform less frequent checks on larger volumes of documents. Because result measures and quality assurance checks are performed using statistical sampling techniques, the larger the volume of material checked at one time, the less checking (in terms of percentage of all submitted material) is actually required.

This approach accommodates both forms of submission: electronic and non-electronic. Non-electronic submissions would be evaluated for submission requirements only (i.e., packaging) and reviewed for DMI and DMP along with electronic submissions when loaded onto the database.

The O&M contractor will report results and passed/failed batches to the CE contractor and LSSA. The reporting will be done by submitted batch, so that this information can be logged with other LSS Participant control information on the batch. The CE contractor will analyze all problem areas and prepare recommendations to the LSSA for further action. Further action may take the form of an on-site audit of processes noted as causing the problems, and LSSA assistance to the LSS Participant in correcting the problems. On-site audits would be used to review non-relevant material from the DMI process, and to evaluate DMP process operations and DMS procedures.

The LSSA will notify LSS Participants of passed/failed batches, communicate the reasons for failure, and identify the errors that must be corrected. LSS Participants must correct all noted errors and rework all failed batches. The notice from the O&M contractor will contain instructions on time frames for resubmitting failed batches.

The LSSA will use the reports provided by the O&M and CE contractors to assess LSS Participants' compliance with the DMI, DMP, and DMS guidance. For those LSS Participants whose performance evidences the use of ineffective processing methods or bad faith, the LSSA may impose warnings, penalties or sanctions.

Warnings issued by the LSSA should be effective in putting LSS Participants on notice that action needs to be taken in order to achieve substantial compliance. Once the LSS is on-line and available for LSS Participant usage, and assuming that the LSS Participants come to depend on it, revocation of access rights may become a powerful means of ensuring further compliance. Warnings may be accompanied by offers of assistance from the LSSA. LSS Participants will have a strong incentive to accept that assistance in order to be considered in substantial compliance.

The LSSA may impose penalties for serious offenders. Any penalties imposed by the LSSA should relate to the LSS Participant's progress toward the goal of 100% completion and substantial compliance. The only two possible areas where penalties might be invoked are

access to the LSS (once it is on-line) and party status in the hearing. Access to the LSS can conceivably be revoked on more than one occasion, if revocations are temporary. This may be a reasonable penalty for non-DOE LSS Participants, since they must rely on the LSS for access to DOE-supplied material. DOE has most of the material to be used in the hearing and has great motivation to remain compliant with the rule, in order to be a party to the hearing. Without DOE, basis for the hearing does not exist. Therefore, party status can be referred to at various times in the context of warnings (for both DOE and non-DOE LSS Participants), but the actual penalty would only be applicable for the most serious, deliberate and repeated offenses, where the indication was that the LSS Participant would not be considered in substantial compliance with the rule.

Since the LSSA exists to assist LSS Participants in becoming and remaining compliant and thus achieving party status, a recommendation to deny party status is, in reality, a loss for both the LSS Participant and the LSSA. Thus, this recommendation should be a last resort.

References

1. The LSS Rule, 10 CFR Part 2

2. Draft Regulatory Guide on the Topical Guidelines

3. The Big Book

4. Memorandum from LSS Administrator dated April 12, 1991, and titled "A Systematic Approach for Managing LSSA Activities that Focuses on Quality Results and Risk Avoidance"

Draft Step 2 Materials

Licensing Support System Administrator's Quality Management Plans

for

Task Area 7 of Contract No. NRC-40-90-346

Task Order No. 2

July 3, 1991

by

LABAT-ANDERSON Incorporated

with

Price Waterhouse

Acronyms Used in Draft Step 2 Materials

ASCII	American Standard Code for Information Interchange
CAR	Compliance Assistance and Reporting
CE	Compliance Evaluation
Commission	Nuclear Regulatory Commission
DLO	Designated LSS Official
DMI	Documentary Material Identification
DMP	Documentary Material Preparation
DMS	Documentary Material Submission
DOE	Department of Energy
HLB	Hearing Licensing Board
HLW	High Level Waste
LSS	Licensing Support System
LSSA	Licensing Support System Administrator
LSSARP	Licensing Support System Advisory Review Panel
NRC	Nuclear Regulatory Commission
OLSSA	Office of the Licensing Support System
O&M	Operations and Maintenance
PALB	Pre-licensing Application Licensing Board
PDLS	Priority Document Loading Schedule
QA	Quality Assurance
QC	Quality Control
QMP	Quality Management Plan

Introduction

This deliverable was developed as Item g, Section I.A.1 of the Task Order No. 2 under Contract No. NRC-40-90-345. This document develops process flow diagrams and performance measures for draft Step 2 materials as part of the Statement of Work (SOW). The SOW states:

> "the contractor shall develop four QMPs following the five steps of the LSSA's Quality Management Approach, as documented in 'A Systematic Approach for Managing LSSA Activities that Focuses on Quality Results and Risk Avoidance.'"

This introduction provides an overview of the four phases required to fully develop the Step 2 materials. The first phase of Step 2 material development is to prepare flow diagrams for the second- and third-level processes of the WBS. These diagrams depict: the activities in the process; the interrelationships among the activities; the process inputs, outputs, suppliers, and customers; and the organizations responsible for performing the process. The second phase of Step 2 development is to state the performance measures for the process objectives that were defined in the Step 1 materials. The objectives have been further developed using a two-tiered approach to facilitate the matching of performance measures to specific objectives. The performance measures provide a quantitative (or qualitative) baseline by which to evaluate progress toward achieving an objective. The third phase is to identify the data needed to measure performance, and the fourth and final phase is to develop a plan for collecting that data.

The following assumptions were used when developing the draft Step 2 materials:

- The quantitative measures used in the draft Step 2 materials are based on the measures presented in the Step 1 Add-on Paper, dated June 14, 1991, regarding definitions of compliance
- The PDLS includes categories of data and their priority status, volume estimates of each participant's holdings of each category, and the schedule for submission of each category
- The LSSA Compliance Evaluation contractor is a separate entity to the LSS O&M contractor.

The draft Step 2 materials are presented for each of the four processes described in Working Paper No. WP-90W00494, December, 1990. The four processes are:

- Documentary Material Identification
- Documentary Material Preparation
- Documentary Material Submission
- Compliance Assistance and Reporting.

Draft Step 2 Materials: Develop Process Flow Diagrams and Performance Measurement Requirements

Documentary Material Identification

2.1 Process Flow Diagrams

Based on thorough examination and analysis, the LABAT-ANDERSON Incorporated / Price Waterhouse (LAI/PW) project team is restructuring the flow diagrams required in the development of Step 2 materials. A complete series of flow diagrams for the identification process is included in the appendix. To maximize the effectiveness of the flow diagrams, they have been modified to read top-to-bottom to convey the sequential aspect of the processes. All inputs are still shown on the left of the processes and the outputs remain on the right. The supplier or customer of each input or output is added to provide additional information. Additionally, in the process boxes, the name of the entity responsible for performing that process is included. The process number, which reflects the process number used in the work breakdown structure, was simply moved from the top of the box to the bottom.

Another addition to the diagrams is naming the interprocess flows (arrows). This is provided to clarify the diagrams and present results in a more thorough analysis of what is being passed from one process to another. Process inputs and outputs are added, deleted, and changed, where necessary, to reflect our current interpretations of what is "in" and "out" of the process. The revisions included in these diagrams, once approved by the OLSSA, will need to be incorporated into the Step 1 materials.

2.2 Performance Measures/Data Needs

Objective 1: Fully involve users (LSSARP) in the development of the DMI guidance, standards and schedule.

Performance Measure: Evidence that LSSARP members are satisfied with their level of involvement in DMI process decisions, including both development and implementation.

Data Needed: Memorandum from the LSSARP reflecting approval of LSSA's proposed activities and schedule for LSSARP involvement in the DMI process.

Data Needed: Memorandum from the LSSARP reflecting comments on LSSA's draft and final DMI Guidance.

Data Needed: Comments and feedback in LSS Participants' regular status reports to LSSA.

Objective 1 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant compliance with DMI.

Objective 2: Produce clear DMI guidance to permit LSS Participants to identify all relevant or potentially relevant LSS documentary material in a complete, consistent, and accurate manner.

Objective 2a: Produce clear guidance to assist LSS Participants in identifying their "universe" of materials to be screened for relevancy.

Performance Measure: Measures of thorough and systematic LSS Participants' plan preparation and implementation (in accordance with the DMI guidance) for identifying all potentially relevant documentary materials.

Data Needed: LSS Participant Compliance Plans.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMI standards as well as documentation concerning any remedial action taken to alleviate such non-compliance.

Objective 2b: Produce clear guidance to assist LSS Participants in making relevancy determinations based on the Commission's *Regulatory Guide on LSS Topical Guidelines.*

Performance Measure: No more than 2% of all documents screened are eliminated from further processing as non-relevant based upon improper application of DMI Guidance.

Data Needed: LSS Participant Compliance Plans.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Monthly reports from LSS O&M contractor concerning the number of non-relevant documents submitted by each LSS Participant.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process, including training program effectiveness.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards including their obligation to maintain all potential documentary material and technical data determined to be "non-LSS qualified" for further review by LSSA.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMI standards as well as documentation concerning any remedial actions taken to alleviate such non-compliance.

Performance Measure: No more than 2% of all documents screened are incorrectly identified as relevant based upon improper application of DMI Guidance.

Data Needed: LSS Participant Compliance Plans.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Objective 2b (cont.)

Data Needed: Monthly reports from LSS O&M contractor concerning the number of non-relevant documents submitted by each LSS Participant.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMI standards as well as documentation concerning any remedial actions taken to alleviate such non-compliance.

Objective 3: Identify all relevant or potentially relevant documentary material in accordance with the schedule contained in their LSSA-approved Compliance Plan in order to ensure the usefulness of the LSS for technical review during the pre-license and licensing phases.

Performance Measure : Evidence that LSS Participants are identifying documentary materials in accordance with the schedule in their Compliance Plan and the PDLS.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards.

Data Needed: Monthly reports from LSSA's O&M contractor comparing submitted and loaded data against the PDLS requirements.

Objective 4: Ensure that there is as little duplication of documentary materials as possible in the LSS resulting from the DMI process.

Performance Measure: LSS Participant Compliance Plans that contain adequate procedures to successfully identify duplicate documentary materials so that no more than 2% of the materials passed to the DMP process are duplicates.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards.

Performance Measure: LSS Participant Compliance Plans that contain adequate procedures to include in the DMI process only the best available copy of materials, where multiple copies exist within their process.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Copies of LSS Participant audits of the effectiveness of their DMI process.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMI standards.

Objective 5: Provide guidance to the LSS Participants to ensure the existence of a suitable basis to retrospectively decide whether relevancy determinations have been made properly.

Objective 5a: Ensure that a suitable record of relevancy determinations is maintained by the LSS Participants.

Performance Measure: Evidence that the LSS Participants Compliance Plans contain adequate procedures for recording the rationale for all relevancy determinations during the DMI process (both for inclusion and exclusion) and that they are effectively implemented.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan (including adequately tracked and recorded DMI activity).

Data Needed: Copies of LSS Participant audits of the effectiveness of their logging and control (tracking) procedures.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with their logging and control procedures as contained in their Compliance Plans.

Objective 5b: Ensure that material rejected for entry into the LSS by the LSS Participants is maintained for review by the LSSA.

Performance Measure: Evidence that the LSS Participants' Compliance Plans contain adequate procedures to maintain the integrity of material rejected for entry into the LSS, to permit LSSA review of those determinations, and that those procedures are being effectively implemented.

Data Needed: LSS Participant Compliance Plans

Objective 5b (cont.)

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan (including adequately tracked and recorded DMI activity).

Data Needed: Copies of LSS Participant audits of the effectiveness of their logging and control (tracking) procedures as they relate to rejected materials.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with their logging and control procedures as contained in their Compliance Plans.

Objective 6: Minimize the risk of willful and inadvertent destruction or diversion of documents during the DMI process.

Performance Measure: Less than 1 % of the documentary material identified as relevant is inadvertently lost or destroyed during the DMI process or during transfer to the DMP process.

Data Needed: LSS Participant reports comparing logs of documents screened with logs of documents prepared, by batch, to determine any discrepancies.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor concerning the adequacy of LSS Participant procedures to prevent inadvertent loss or destruction of screened materials.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been identified and tracked in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Performance Measure: Evidence that no documentary material otherwise relevant and acceptable for entry into the LSS has been willfully destroyed or diverted during the DMI process.

Data Needed: Certifications, every six months, by each LSS Participants' DLO that all documentary material has been identified in accordance with the DMI guidance.

Objective 6 (cont.)

Data Needed:	Copies of LSS Participants' audits of the effectiveness of their internal controls in preventing willful destruction or diversion.
Data Needed:	Audit reports from the LSSA Compliance Evaluation contractor on the effectiveness of LSS Participants' internal control in preventing willful destruction or diversion.
Data Needed:	Ad-hoc notification to LSSA by LSS users that certain data are not in the LSS that they anticipated should be in the LSS.
Data Needed:	Documented allegations that LSS data has been willfully destroyed or diverted.

2.3 Information Collection Plan

Information to be collected in this program fall into 10 categories:

1. "Compliance Program Plans" provided by LSS Participants. Information relative to DMI performance measures that should be included in LSS Participants' plans and communicated to the LSSA includes:

   - DMI procedures
   - training for DMI
   - internal logging and control procedures
   - audit plan for self audit of DMI activities
   - LSS Participant plan for managing the DMI process, including identifying process flaws and errors, correcting them and reporting corrections to the LSSA.

2. Six month certifications prepared by each LSS Participant's DLO. The information required from the LSS Participant DLO's includes:

   - certification that all data required by the PDLS in each document category has been identified, or explanation of causes of deficiency
   - certification that all data has been identified in accordance with the DMI guidance

- copies of control logs showing adequate tracking of all material screened, including both included and excluded materials.

3. LSS Participant audit reports. LSS Participant audit reports should include items such as:

   - identification of any problems encountered in the DMI process, and corrective actions taken
   - comments on the effectiveness of internal controls in preventing willful destruction or diversion of documents.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans. The types of information reported may include:

   - comparison of their production rates against their Compliance Plan schedule
   - summary of the number of batches transferred to the DMP process
   - summary of the materials processed.

5. Other LSS Participant communications. Other communications may include:

   - written explanations of causes for not being able to follow the DMI guidance
   - written reports of the discovery and correction of process flaws which, if not corrected would prevent the LSS Participant from following the DMI guidance and/or their compliance plans
   - written reports of process flaws that have caused the Participant to fall behind in DMI volume
   - LSS user communications related missing LSS data.

6. Allegations of wrongdoing by LSS Participants. These may be:

   - reports by employees of an LSS Participant
   - reports from the LSS O&M contractor
   - formal complaints filed by other LSS Participants or LSS parties.

7. LSSARP memos. Memos may be required to document LSSARP approval in areas such as:

   - approval of the DMI guidance and expression of satisfaction that their advice has been implemented
   - approval of LSSA level of assistance to LSS Participants
   - approval of the PDLS and expression of satisfaction that following the PDLS will result in all relevant documents being loaded.

8. LSSA Compliance Evaluation contractor audit reports. These may include the following types of information:

   - comments on the effectiveness of LSS Participants' DMI processes
   - comments on the effectiveness of participants' internal controls in preventing inadvertent loss or destruction of documents during the DMI process or during transfer to the DMP process
   - comments on the effectiveness of LSS Participants' internal controls in preventing willful destruction or diversion of documents during the DMI process or during transfer to the DMP process
   - comments on how well the LSS Participants are following their compliance plans with respect to DMI
   - memorandum (addressed to the file) for all process malfunctions easily resolved or to the LSSARP if further action (such as changes to the guidance or PDLS) is required.

9. LSSA status reports to LSSARP. The LSSA status reports may include:

   - status of assistance being provided to LSS Participants
   - discovery and correction of process flaws.

10. Monthly and summary reports by LSS O&M contractor. The information provided in O&M contractor reports should at a minimum include:

    - a record of non-relevant documentary materials submitted by each LSS Participant and identified at the capture station or upon on-line review of submitted material in the LSS

- a record of the number of batches rejected for reasons relating to improper DMI processing
- recommendations on changes to the DMI process to prevent similar problems in future batches
- summary reports in the form of sorted summaries of the LSS documents organized by different sort criteria (such as subject or date).

The plan for collecting data in each of these categories follows:

1. "Compliance Program Plans" provided by LSS Participant. The LSSA must notify LSS Participants of the need and schedule of submission for specific information.

2. Six month certifications by each LSS Participant's DLO. The LSSA must notify LSS Participants of the specific information needed in their six-month reports and the format for reporting results data.

3. LSS Participant audit reports. Each LSS Participant must submit an audit plan as part of their Compliance Program Plan. LSSA must make it a requirement that LSS Participants provide the LSSA with copies of these reports at regular intervals as determined under their audit plans.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans. The LSSA must determine how compliance information should be reported, how often and to whom. The LSSA must specify the types of information to be reported.

5. Other LSS Participant communications. The LSSA must inform LSS Participants of events that may require them to communicate outside of the formal reporting structure. These events should be specified, as well as the procedures for reporting and the information that must be reported. The LSSA must assure that users are informed of how and where to submit questions when they suspect that data is missing from the LSS.

6. Allegations of wrongdoing by LSS Participants. Allegations of wrongdoing with respect to submission practices may come from within an LSS Participant organization, from another LSS Participant or from the LSS O&M contractor. LSSA must establish a confidential reporting process. This reporting scheme must be included in LSS Participants' training programs for all employees with responsibility for any phase of the DMI process. It should encompass both insider reporting and reporting by one party on another. The LSSA should always be informed of these allegations, even if they are made more formally as part of the hearing process.

7. LSSARP memos. The LSSA should notify the LSSARP of issues that require their formal approval. Approval points should be built into the schedule for developing the guidance and Participant compliance plans, and the LSSA should actively pursue obtaining these approvals.

8. LSSA Compliance Evaluation contractor audit reports. LSSA must obtain auditing assistance from a qualified contractor. A specific audit plan must be developed and implemented, taking into account the schedule for reporting on LSS Participant compliance to the Commission.

9. LSSA status reports to LSSARP. In order to maximize the ability of the LSSARP to provide advice, the LSSA will periodically meet with them and report on the status of LSS development and LSS Participant compliance.

10. Monthly and summary reports by LSS O&M contractor. The LSSA will require the LSS O&M contractor to submit monthly reports containing operational and evaluation data that will help the LSSA in determining levels of compliance and how the LSS development is proceeding according to plan. From time to time the LSSA may request special reports from the LSS O&M contractor listing the contents of the LSS. The LSSA will use these reports to help him determine LSS Participants' compliance with the DMI process, and also to assess that the intent of the Rule is being met with respect to DMI.

2.4 Information / Record Keeping Requirements

The LSSA will retain all records containing information collected or generated under this plan in accordance with Commission records retention and disposal requirements, including any special needs of the HLW licensing process as determined by the PALB, the HLB and the Commission. LSSA contractors will maintain all records relating to their activities in accordance with the terms of their contracts and will notify the LSSA before destroying any records. LSSA will determine which contract records should be retained in accordance with Commission records retention and disposal requirements. LSS Participants will keep process records for a minimum of 1 year after either (1) the completion of the HLW licensing process or (2) the termination of their involvement in the HLW licensing process.

Draft Step 2 Materials: Develop Process Flow Diagrams and Performance Measurement Requirements

Documentary Material Preparation

2.1 Process Flow Diagrams

Based on thorough examination and analysis, the LAI/PW project team is restructuring the flow diagrams required in the development of Step 2 materials. A complete series of flow diagrams for the preparation process is included in the appendix. To maximize the effectiveness of the flow diagrams, they have been modified to read top-to-bottom to convey the sequential aspect of the processes. All inputs are still shown on the left of the processes and the outputs remain on the right. The supplier or customer of each input or output is added to provide additional information. Additionally, in the process boxes, the name of the entity responsible for performing that process is included. The process number, which reflects the process number used in the work breakdown structure, was simply moved from the top of the box to the bottom.

Another addition to the diagrams is naming the interprocess flows (arrows). This is provided to clarify the diagrams and present results in a more thorough analysis of what is being passed from one process to another. Process inputs and outputs are added, deleted, and changed, where necessary, to reflect our current interpretations of what is "in" and "out" of the process. The revisions included in these diagrams, once approved by the OLSSA, will need to be incorporated into the Step 1 materials.

2.2 Performance Measures/Data Needs

Objective 1: Fully involve users (LSSARP) in the development of DMP guidance, standards, and schedules

Performance Measure: Evidence that LSSARP members are satisfied with their level of involvement in DMP process decisions, including both development and implementation

Data Needed: Memorandum from the LSSARP reflecting approval of LSSA's proposed activities and schedule for LSSARP involvement in the DMP process

Data Needed: Memorandum from the LSSARP reflecting comments on the LSSA's draft and final DMP Guidance, standards, and schedules

Data Needed: Comments and feedback in LSS Participants' regular status reports to LSSA.

Objective 1 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant compliance with DMP.

Objective 2: Produce clear DMP guidance to permit LSS Participants to completely, consistently, and accurately prepare all the identified backlog and "contemporaneously generated" LSS documentary material, including header standards, header records, indexing rules, special fields for adjudicatory materials, image rules, image specifications, ASCII format standards, authority files, and unitization rules.

Objective 2a: Provide clear guidance to enable LSS Participants to completely, consistently, and accurately prepare identified documentary material for entry into the LSS.

Performance Measure: Evidence that the DMP Guidance is understood and being effectively applied by the LSS Participants

Data Needed: Memorandum from the LSSARP reflecting its approval of the DMP guidance

Data Needed: LSS Participant feedback while they are drafting their plans, preparing materials for submission, and using the system to retrieve known items

Data Needed: Monthly reports from LSSA's O&M contractor containing LSS operational data

Data Needed: Logs of questions from LSS Participant documentary material preparers on how to apply the guidance to headers, images, or ASCII conversions

Data Needed: Record of incorrect preparation of headers, images, and ASCII conversions forwarded for submission to the LSS

Data Needed: Record of LSS Participants incorrectly verifying record headers, images, ASCII conversions submitted to the LSS

Objective 2b: Provide clear guidance to the LSS Participants to ensure the the accuracy of DMP activities.

Performance Measure: No less than 98% accuracy in preparing headers and scanning images; a level of accuracy in creating ASCII full text documents which reflects the prevailing technological standards; 100 percent accuracy in matching headers to ASCII full text and images; and 100% completion of document preparation to account for 100% of all backlog determined relevant.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been characterized in accordance with LSS guidance on DMP

Data Needed: Copies of LSS Participants' internal audits of the effectiveness of the preparation process

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' DMP training program effectiveness

Data Needed: Reports from the LSS O&M contractor of LSS Participants' data reflecting the content of header records, and image/ASCII submission

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant compliance with DMP guidance and standards

Data Needed: Logs of Participant calls to O&M contractor requesting assistance with applying the DMP guidance to their documentary material submissions

Objective 3: Establish a reasonable balance between header design and the application of indexing rules to achieve maximum documentary material throughput

Performance Measure: Measure the ability of the Participants to create header records using the indexing protocols established in the DMP guidance in accordance with their Compliance Plan.

Objective 3 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant's compliance with DMP guidance and standards.

Data Needed: Logs of LSS Participant's calls to O&M contractor requesting assistance with applying the DMP guidance to the header records.

Data Needed: LSSA's O&M contractor records of incorrect preparation of header records.

Data Needed: Copies of the LSS Participant's internal audits of the effectiveness of the preparation process.

Data Needed: LSS Participant's internal DMP process logs showing data for documentary material headers.

Objective 4: Prepare and verify all identified documentary material in accordance with the schedule defined in the LSS Participant Compliance Plan and the PDLS to ensure the usefulness of the LSS for technical review during the pre-license and licensing phases.

Performance Measure: 100% of all documentary material is prepared in accordance with the schedule defined in the LSS Participant Compliance Plan and the PDLS.

Data Needed: LSS Participants Compliance Plan

Data Needed: Monthly reports from LSSA's O&M contractor containing LSS operational data

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participant compliance with DMP Guidance and standards, including a comparison of document dates to the date prepared for submission for "contemporaneously generated" documentary materials.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been prepared in accordance with the DMP guidance

Objective 4 (cont.)

Data Needed: Certifications, every six months, by each LSS Participants' DLO that all data has been prepared in accordance with the LSS PDLS

Objective 5: Minimize the risk of willful or inadvertent destruction or diversion of documents during the DMP process

Performance Measure: Less than 1% of the documentary material identified is inadvertently lost or destroyed during the DMP process or during transfer to the DMS process.

Data Needed: LSS Participant reports comparing logs of documents identified with logs of documents submitted, by batch, to determine discrepancies.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor concerning adequacy of LSS Participant procedures to prevent inadvertent loss or destruction of documentary materials during the DMP process.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all documentary material has been prepared and tracked in accordance with the LSS rule, Section 2.1003, and their Compliance Plan.

Performance Measure: No documentary material prepared for entry into the LSS has been willfully destroyed or diverted during the DMP process.

Data Needed: Certifications, every six months, by each LSS Participants' DLO that all data has been prepared in accordance with OLSSA's guidance.

Data Needed: Copies of LSS Participants audits of the effectiveness of their internal controls to prevent willful destruction or diversion of documentary materials during the DMP process.

Objective 5 (cont.)

Data Needed:	Audit reports from the LSSA Compliance Evaluation contractor on the effectiveness of LSS Participants' internal controls to prevent willful destruction or diversion
Data Needed:	Ad-hoc notification to LSSA by LSS users that certain data are not in the LSS that they anticipated should be in the LSS
Data Needed:	Allegations that LSS data have been willfully destroyed or diverted

2.3 Information Collection Plan

Information to be collected in this program falls into 10 categories:

1. "Compliance Program Plans" provided by LSS Participants. Information relative to DMP performance measures that should be included in LSS Participants' plans and communicated to the LSSA includes:

   - DMP procedures
   - training for DMP
   - internal logging and control procedures
   - audit plan for self audit of DMP activities
   - LSS Participant plan for managing the DMP process, including identifying process flaws and errors, correcting them and reporting corrections to the LSSA.

2. Six month certifications prepared by each LSS Participant's DLO. The information needed from the LSS Participant DLO's includes:

   - certification that all data required by the PDLS in each document category has been prepared, or an explanation of the causes of deficiency
   - certification that all data has been prepared for submission in accordance with the DMP guidance
   - copies of control logs showing what was prepared.

3. LSS Participant audit reports. LSS Participant audit reports should include items such as:

   - identification of any problems encountered in the DMP processes, and corrective actions taken

   - comments on the effectiveness of internal controls in preventing willful destruction or diversion of documentary materials.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans. The types of information reported may include:

   - measures of their preparation rates against the PDLS

   - summary of the number of batches prepared and accepted or rejected and reworked

   - summary of the materials prepared (e.g. copies of indexes prepared under the packaging guidance).

5. Other LSS Participant communications. Other communications may include:

   - written explanations of causes for not being able to follow the DMP guidance

   - written reports of the discovery and correction of process flaws which, if not corrected would prevent the LSS Participant from following the DMP guidance and/or their compliance plans

   - written reports of process flaws that have caused the LSS Participant to fall behind in preparation volume

   - LSS user communications concerning missing LSS data.

6. Allegations of wrongdoing by LSS Participants. These may be:

   - reports by employees of a LSS Participant

   - reports from the LSS O&M contractor

   - formal complaints filed by other LSS Participants or LSS parties.

7. LSSARP memos. Memos may be required to document LSSARP approval in areas such as:

- approval of the DMP guidance and expression of satisfaction that their advice has been implemented
- approval of LSSA's level of assistance to LSS Participants
- approval of the PDLS and expression of satisfaction that following the PDLS will result in all relevant documents being loaded.

8. LSSA Compliance Evaluation contractor audit reports. These may include the following types of information:

- comments on the effectiveness of LSS Participants' DMP processes
- comments on the effectiveness of LSS Participants' internal controls in preventing inadvertent loss or destruction of documentary material during the DMP process or during transfer to the DMS process
- comments on the effectiveness of the LSS Participants' internal controls in preventing willful loss or destruction of documentary material during the DMP process
- comments on how well the LSS Participants are following their compliance plans with respect to preparation
- memorandum (addressed to the file) for all process malfunctions easily resolved or to the LSSARP if further action (such as changes to the guidance or PDLS) is required.

9. LSSA status reports to LSSARP. The LSSA status reports may include:

- status of assistance being provided to LSS Participants
- discovery and correction of process flaws
- analysis of areas where preparation is falling behind the PDLS.

10. Monthly and summary reports by LSS O&M contractor. The information provided in O&M contractor reports may include:

- comparison of prepared data against standards established in the DMP guidance
- a record of the number of batches received and accepted, the number of batches rejected and reasons for rejection
- a record of exceptions noted during the preparation process, and what was done to resolve them
- recommendations on changes to the DMP process to prevent similar exceptions in future batches
- comparison of documents prepared to LSS Participant logs
- results of investigations of any apparent discrepancies between documents prepared and LSS Participant control logs that may indicate a document was lost or destroyed
- comparison of the number of documents prepared by document category to the scheduled amount in the PDLS and analysis of any substantial (more than 10%) discrepancies
- summary reports in the form of sorted summaries of the LSS documents organized by different sort criteria (such as subject or date).

The plan for collecting data in each of these categories follows:

1. "Compliance Program Plans" provided by LSS Participant: The LSSA must notify LSS Participants of the specific information needed and when it will be needed.

2. Six month certifications prepared by each LSS Participant's DLO: The LSSA must notify LSS Participants of the specific information needed in their six-month reports, the format for reporting results data, and the schedule of report due dates.

3. LSS Participant audit reports: Each LSS Participant must submit an audit plan to be approved by the LSSA as part of their Compliance Program Plan. LSSA must make it a requirement that LSS Participants provide the LSSA with copies of these reports at regular intervals as determined under their audit plans.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans: The LSSA must determine how compliance information should be reported, how often, and to whom. The LSSA must specify the types of information to be reported.

5. Other LSS Participant communications: The LSSA must inform LSS Participants of events that may require them to communicate outside of the formal reporting structure. These events should be specified, as well as the procedures for reporting and the information that must be reported. The LSSA must assure that users are informed of how and where to submit questions when they suspect that data is missing from the LSS.

6. Allegations of wrongdoing by LSS Participants: Allegations of wrongdoing with respect to preparation practices may come from within an LSS Participant organization, from another LSS Participant, or from the LSS O&M contractor. LSSA must establish a confidential reporting scheme. This reporting scheme must be included in LSS Participants' training programs for all employees with responsibility for preparing documents. It should encompass both insider reporting and reporting by one party on another. The LSSA should always be informed of these allegations, even if they are made more formally as part of the hearing process.

7. LSSARP memos: The LSSA should notify the LSSARP of issues that require their formal approval. Approval points should be built into the schedule for developing the guidance and LSS Participant compliance plans, and the LSSA should actively pursue obtaining these approvals.

8. LSSA Compliance Evaluation contractor audit reports: LSSA must obtain auditing assistance from a qualified contractor. A specific audit plan must be developed and implemented, taking into account the schedule for reporting on LSS Participant compliance to the Commission.

9. LSSA status reports to LSSARP: In order to maximize the ability of the LSSARP to provide advice, the LSSA will periodically meet with them and report on the status of LSS development and LSS Participant compliance.

10. Monthly and summary reports by LSS O&M contractor: The LSSA will require the LSS O&M contractor to submit monthly reports containing operational and evaluation data that will help the LSSA in determining levels of compliance and how the LSS development is proceeding according to plan. From time to time the LSSA may request special reports from the LSS O&M contractor listing the contents of the LSS. The LSSA will use these reports to help him determine LSS Participants' compliance with the DMP process, and also to assess that the intent of the Rule is being met with respect to DMP.

2.4 Information / Record Keeping Requirements

The LSSA will retain all records containing information collected or generated under this plan in accordance with Commission records retention and disposal requirements, including any special needs of the HLW licensing process as determined by the PALB, the HLB and the Commission. LSSA contractors will maintain all records relating to their activities in accordance with the terms of their contracts and will notify the LSSA before destroying any records. LSSA will determine which contract records should be retained in accordance with Commission records retention and disposal requirements. LSS Participants will keep process records for a minimum of 1 year after either (1) the completion of the HLW licensing process or (2) the termination of their involvement in the HLW licensing process.

Draft Step 2 Materials: Develop Process Flow Diagrams and Performance Measurement Requirements

Documentary Material Submission

2.1 Process Flow Diagrams

Based on thorough examination and analysis, the LAI/PW project team is restructuring the flow diagrams required in the development of Step 2 materials. A complete series of flow diagrams for the submission process is included in the appendix. To maximize the effectiveness of the flow diagrams, they have been modified to read top-to-bottom to convey the sequential aspect of the processes. All inputs are still shown on the left of the processes and the outputs remain on the right. The supplier or customer of each input or output is added to provide additional information. Additionally, in the process boxes, the name of the entity responsible for performing that process is included. The process number, which reflects the process number used in the work breakdown structure, was simply moved from the top of the box to the bottom.

Another addition to the diagrams is naming the interprocess flows (arrows). This is provided to clarify the diagrams and present results in a more thorough analysis of what is being passed from one process to another. Process inputs and outputs are added, deleted, and changed, where necessary, to reflect our current interpretations of what is "in" and "out" of the process. The revisions included in these diagrams, once approved by the OLSSA, will need to be incorporated into the Step 1 materials.

2.2 Performance Measures/Data Needs

Objective 1: Fully involve users (LSSARP) in the development of the DMS guidance, standards and schedule.

Performance Measure:	Evidence that LSSARP members are satisfied with their level of involvement in DMS process decisions, including both development and implementation.
Data Needed:	Memorandum from LSSARP reflecting approval of LSSA's proposed activities and schedule for LSSARP involvement in the DMS process.
Data Needed:	Memorandum from the LSSARP reflecting comments on the draft and final DMS Guidance.
Data Needed:	Comments and feedback in LSS Participants' regular status reports to LSSA.

Objective 1 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant compliance with DMS.

Objective 2: Produce clear DMS guidance to permit LSS Participants to properly submit all relevant or potentially relevant LSS documentary material in a complete, consistent, and accurate manner.

Objective 2a.: Produce clear guidance concerning electronic submissions.

Performance Measure: Evidence that electronic submissions result in acceptable LSS data 98 % of the time.

Data Needed: Memorandum from the LSSARP indicating that they have consulted with Commission staff and conclude that 1) the PDLS sufficiently encompasses the document categories described in the Topical Guidelines and 2) following the PDLS will result in all relevant documents being loaded.

Data Needed: LSS Participant Compliance Plans.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Monthly reports from LSS O&M contractor comparing the number of documents submitted by each LSS Participant with the scheduled amount for each document category identified in the PDLS.

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMS standards.

Objective 2b: Produce clear guidance concerning non-electronic submissions.

Performance Measure: Evidence that the submission of non-electronic materials results in acceptable LSS data 98 % of the time.

Data Needed: Memo from the LSSARP indicating that they have consulted with Commission staff and conclude that 1) the PDLS sufficiently encompasses the document categories described in the Topical Guidelines and 2) following the PDLS will result in all relevant documents being loaded.

Data Needed: LSS Participant Compliance Plans.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Monthly reports from LSS O&M contractor comparing the number of documents submitted by each LSS Participant with the scheduled amount for each document category identified in the PDLS.

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMS standards.

Objective 2c: Produce an effective PDLS for the use of LSS Participants in submitting LSS documentary materials.

Performance Measure: Evidence that documents are being loaded in order of their relative importance to the licensing proceeding in accordance with the PDLS.

Data Needed: Memo from the LSSARP indicating that they have consulted with Commission staff and conclude that following the PDLS will ensure that documents are loaded in order of their relative importance to the licensing procedure.

Data Needed: LSS Participant Compliance Plans.

Objective 2c (cont.)

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Monthly reports from LSS O&M contractor comparing the number of documents submitted by each LSS Participant with the scheduled amount for each document category identified in the PDLS.

Performance Measure: Evidence that enough documents are being loaded so that DOE certification can occur six months before submission of the license application.

Data Needed: Memo from the LSSA to the LSS Participants indicating that following the PDLS will result in enough documents being loaded so that DOE certification can occur six months before submission of the application.

Data Needed: Monthly reports from LSS O&M contractor comparing the number of documents submitted by each LSS Participant with the scheduled amount for each document category identified in the PDLS.

Objective 2d: Provide sufficient guidance concerning access protocols for technical data to ensure the reasonable availability of those materials.

Performance Measure: Evidence that the access protocols ensure the reasonable availability of subject materials.

Data Needed: LSS O&M contractor review of LSS Participants' headers for technical data to determine whether the information provided is sufficient to indicate where the materials are stored and how access may be obtained.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' storage of and procedures for accessing (or allowing access to) technical data.

Objective 3: Submit all prepared documentary material accurately and in accordance with the schedule contained in the LSS Participant's Compliance Plan in order to ensure the usefulness of the LSS for technical review during the pre-license and licensing phases.

Performance Measure: Evidence that LSS Participants' are submitting LSS materials in accordance with the schedule contained in their Compliance Plan and the PDLS.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Periodic DLO DMS production reports

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMS standards and the PDLS.

Data Needed: Monthly reports from LSSA's O&M contractor comparing submitted and loaded data against the DMS packaging standards, access protocols, and other guidance.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMS standards as well as documentation concerning any remedial actions taken to alleviate such non-compliance.

Data Needed: LSS Participants' written explanations of causes for deviation from the DMS Guidance.

Performance Measure: 100% of relevant documentary material estimated at the time an LSS Participant is initially granted LSS access are properly submitted six months before DOE applies for the HLW license (DOE) and before party status can be requested (non-DOE Participants).

Data Needed: LSS Participant Compliance Plans

Objective 3 (cont.)

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Periodic DLO DMS production reports

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMS standards.

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Data Needed: Monthly reports from LSSA's O&M contractor comparing submitted and loaded data against the DMS packaging standards, access protocols, and other guidance.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMS standards as well as documentation concerning any remedial actions taken to alleviate such non-compliance.

Data Needed: LSS Participants' written explanations of causes for deviation from the DMS guidance.

Performance Measure: "Contemporaneously generated" documentary materials are submitted in accordance with LSSA-established standards and schedules.

Data Needed: LSS Participant Compliance Plans

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Periodic DLO DMS production reports

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' compliance with DMS standards.

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Objective 3 (cont.)

Data Needed: Monthly reports from LSSA's O&M contractor comparing submitted and loaded data against the DMS packaging standards, access protocols, and other guidance.

Data Needed: Documentation concerning any finding by the LSSA that an LSS Participant is non-compliant with DMS standards as well as documentation concerning any remedial actions taken to alleviate such non-compliance.

Data Needed: LSS Participants' written explanations of causes for deviation from the DMS guidance.

Objective 4: Provide guidance to the LSS Participants to ensure the existence of a suitable basis (a complete record of the timing and content of each batch submitted) to retrospectively decide whether submissions have been properly made.

Performance Measure: Evidence that each LSS Participant has, as part of their compliance plan, an effective logging and control procedure built into its DMS compliance plan.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' logging and control procedures and assessment of their ability to follow documentary material from its entry into the DMS process through its submission.

Performance Measure: Evidence that the use of the logging and control procedures yields a complete record of the timing and content of all submissions.

Data Needed: Monthly reports by the LSS O&M contractor comparing the documents that were loaded against logs maintained by the LSS Participants and submitted as part of the submission packages.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of control points (that is, the points at which control of the document changes) and comparison of findings to control logs.

Objective 4 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of any discrepancies between control logs and documents loaded.

Objective 5: Minimize the risk of inadvertent and willful destruction or diversion of documents during the DMS process.

Performance Measure: Evidence that submission and loading procedures ensure the integrity of the database.

Data Needed: Monthly reports by the LSS O&M contractor of exceptions recorded during the loading process and actions taken to resolve them.

Performance Measure: Less than 1 % of the data originally identified is inadvertently lost or destroyed through the submission process.

Data Needed: Monthly reports by the LSS O&M contractor comparing the documents that were loaded against logs maintained by the LSS Participants and submitted as part of the submission package.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor analyzing any data which, from a comparison of the operational data to the control logs, appears to be lost or destroyed.

Data Needed: Certifications, every six months, by each LSS Participant's DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.

Data Needed: Periodic DLO DMS production reports

Data Needed: Copies of LSS Participant audits of the effectiveness of their submission processes.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of the effectiveness of the LSS Participants' internal controls in preventing the inadvertent destruction or diversion of documentary materials during the DMS process.

Objective 5 (cont.)

Performance Measure:	Evidence that no documentary material otherwise relevant and acceptable for entry into the LSS has been willfully destroyed or diverted during the DMS process.
Data Needed:	Certifications, every six months, by each LSS Participants' DLO that all data has been submitted in accordance with the LSS Rule, Section 2.1003, and their Compliance Plan.
Data Needed:	Copies of LSS Participants' audits of the effectiveness of their internal controls in preventing willful destruction or diversion.
Data Needed:	Audit reports from the LSSA Compliance Evaluation contractor on the effectiveness of LSS Participants' internal control in preventing willful destruction or diversion.
Data Needed:	Ad-hoc notification to LSSA by LSS users that certain data are not in the LSS that they anticipated should be in the LSS.
Data Needed:	Allegations that LSS data has been willfully destroyed or diverted.
Data Needed:	Monthly reports by the LSS O&M contractor comparing the documents received to the PDLS and offering their opinions as to any potential gaps in submissions.

2.3 Information Collection Plan

Information to be collected in this program fall into 10 categories:

1. "Compliance Program Plans" provided by LSS Participants. Information relative to DMS performance measures that should be included in LSS Participants' plans and communicated to the LSSA includes:

   - DMS procedures
   - training for DMS
   - internal logging and control procedures
   - audit plan for self audit of DMS activities

- LSS Participant plan for managing the DMS process, including identifying process flaws and errors, correcting them and reporting corrections to the LSSA.

2. Six month certifications prepared by each LSS Participant's DLO. The information needed from the LSS Participant DLO's includes:

   - certification that all data required by the PDLS in each document category has been submitted, or explanation of causes for becoming behind in submission volume

   - certification that all data has been submitted and packaged for submission in accordance with the DMS guidance

   - copies of control logs showing what was submitted.

3. LSS Participant audit reports. LSS Participant audit reports should include items such as:

   - identification of any problems encountered in submission processes, and corrective actions taken

   - comments on the effectiveness of internal controls in preventing willful destruction or diversion of documents.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans. The types of information reported may include:

   - measures of their submission rates against the PDLS

   - summary of the number of batches submitted and accepted or rejected and reworked

   - summary of the materials submitted (e.g., copies of indexes prepared under the packaging guidance).

5. Other LSS Participant communications. Other communications may include:

   - written explanations of causes for not being able to follow the DMS guidance

   - written reports of the discovery and correction of process flaws which, if not corrected would prevent the LSS Participant from following the DMS guidance and/or their compliance plans

   - written reports of process flaws that have caused the LSS Participant to fall behind in submission volume

- LSS user communications related to data missing from the LSS, in the form of questions filed with the OLSSA.

6. Allegations of wrongdoing by LSS Participants. These may be:

   - reports by employees of an LSS Participant
   - reports from the LSS O&M contractor
   - formal complaints filed by other LSS Participants or LSS parties.

7. LSSARP memos. Memos may be required to document LSSARP approval in areas such as:

   - approval of the DMS guidance and expression of satisfaction that their advice has been implemented
   - approval of LSSA level of assistance to LSS Participants
   - approval of the PDLS and expression of satisfaction that following the PDLS will result in all relevant documents being loaded.

8. LSSA Compliance Evaluation contractor audit reports. These may include the following types of information:

   - comments on the effectiveness of LSS Participants' DMS processes
   - comments on the effectiveness of LSS Participants' internal controls in preventing inadvertent loss or destruction of documentary material during the DMS process.
   - comments on the effectiveness of LSS Participants' internal controls in preventing willful destruction or diversion of documents
   - comments on how well the LSS Participants are following their compliance plans with respect to DMS
   - memorandum (addressed to the file) for all process malfunctions easily resolved or to the LSSARP if further action (such as changes to the guidance or PDLS) is required.

9. LSSA status reports to LSSARP. The LSSA status reports may include:

   - status of assistance being provided to LSS Participants

- discovery and correction of process flaws
- analysis of areas where submission is falling behind the PDLS.

10. Monthly and summary reports by LSS O&M contractor. The information provided in O&M contractor reports may include:

    - comparison of submitted and loaded data against standards established in the DMS guidance
    - a record of the number of batches received and accepted, the number of batches rejected and reasons for rejection
    - a record of exceptions noted during the loading process, and what was done to resolve them
    - recommendations on changes to the DMS process to prevent similar exceptions in future batches
    - comparison of documents loaded to LSS Participant-prepared logs
    - results of investigations of any apparent discrepancies between documents loaded and LSS Participant control logs that may indicate a document was lost or destroyed
    - comparison of the number of documents submitted by document category to the scheduled amount in the PDLS and analysis of any substantial discrepancies
    - summary reports in the form of sorted summaries of the LSS documents organized by different sort criteria (such as subject or date).

The plan for collecting data in each of these categories follows:

1. "Compliance Program Plans" provided by LSS Participant. The LSSA must notify LSS Participants of the need and schedule of submission for specific information.

2. Six month certifications prepared by each LSS Participant's DLO. The LSSA must notify LSS Participants of the specific information needed in their six-month reports and the format for reporting results data.

3. LSS Participant audit reports. Each LSS Participant must submit an audit plan as part of their Compliance Program Plan. LSSA must make it a requirement that LSS Participants provide the LSSA with copies of these reports at regular intervals as determined under their audit plans.

4. LSS Participants' reports comparing actual results with their Compliance Program Plans. The LSSA must determine how compliance information should be reported, how often and to whom. The LSSA must specify the types of information to be reported.

5. Other LSS Participant communications. The LSSA must inform LSS Participants of events that may require them to communicate outside of the formal reporting structure. These events should be specified, as well as the procedures for reporting and the information that must be reported. The LSSA must assure that users are informed of how and where to submit questions when they suspect that data is missing from the LSS.

6. Allegations of wrongdoing by LSS Participants. Allegations of wrongdoing with respect to submission practices may come from within an LSS Participant organization, from another LSS Participant or from the LSS O&M contractor. LSSA must establish a confidential reporting scheme. This reporting scheme must be included in LSS Participants' training programs for all employees with responsibility for submitting documents. It should encompass both insider reporting and reporting by one party on another. The LSSA should always be informed of these allegations, even if they are made more formally as part of the hearing process.

7. LSSARP memos. The LSSA should notify the LSSARP of issues that require their formal approval. Approval points should be built into the schedule for developing the guidance and LSS Participant compliance plans, and the LSSA should actively pursue obtaining these approvals.

8. LSSA Compliance Evaluation contractor audit reports. LSSA must obtain auditing assistance from a qualified contractor. A specific audit plan must be developed and implemented, taking into account the schedule for reporting on LSS Participant compliance to the Commission.

9. LSSA status reports to LSSARP. In order to maximize the ability of the LSSARP to provide advice, the LSSA will periodically meet with them and report on the status of LSS development and LSS Participant compliance.

10. Monthly and summary reports by LSS O&M contractor. The LSSA will require the LSS O&M contractor to submit monthly reports containing operational and evaluation data that will help the LSSA in determining levels of compliance and how the LSS development is proceeding according to plan. From time to time the LSSA may request special reports from the LSS O&M contractor listing the contents of the LSS. The LSSA will use these

reports to help him determine LSS Participants' compliance with the DMS process, and also to assess that the intent of the Rule is being met with respect to DMS.

2.4 Information / Record Keeping Requirements

The LSSA will retain all records containing information collected or generated under this plan in accordance with Commission records retention and disposal requirements, including any special needs of the HLW licensing process as determined by the PALB, the HLB and the Commission. LSSA contractors will maintain all records relating to their activities in accordance with the terms of their contracts and will notify the LSSA before destroying any records. LSSA will determine which contract records should be retained in accordance with Commission records retention and disposal requirements. LSS Participants will keep process records for a minimum of 1 year after either (1) the completion of the HLW licensing process or (2) the termination of their involvement in the HLW licensing process.

Draft Step 2 Materials: Develop Process Flow Diagrams and Performance Measurement Requirements

Compliance Assistance and Reporting

2.1 Process Flow Diagrams

Based on thorough examination and analysis, the LAI/PW project team is restructuring the flow diagrams required in the development of Step 2 materials. A complete series of flow diagrams for the compliance assistance and reporting process is included in the appendix. To maximize the effectiveness of the flow diagrams, they have been modified to read top-to-bottom to convey the sequential aspect of the processes. All inputs are still shown on the left of the processes and the outputs remain on the right. The supplier or customer of each input or output is added to provide additional information. Additionally, in the process boxes, the name of the entity responsible for performing that process is included. The process number, which reflects the process number used in the work breakdown structure, was simply moved from the top of the box to the bottom.

Another addition to the diagrams is naming the interprocess flows (arrows). This is provided to clarify the diagrams and present results in a more thorough analysis of what is being passed from one process to another. Process inputs and outputs are added, deleted, and changed, where necessary, to reflect our current interpretations of what is "in" and "out" of the process. The revisions included in these diagrams, once approved by the OLSSA, will need to be incorporated into the Step 1 materials.

2.2 Performance Measures/Data Needs

Objective 1: Fully involve users (LSSARP) and Commission in the development of the CAR strategy, guidance, standards, and schedule.

Performance Measure: Evidence that LSSARP members are satisfied with their level of involvement in the development and implementation of the CAR process.

Data Needed: Memorandum from LSSARP reflecting approval of LSSA's CAR strategy and schedule for LSSARP involvement in the CAR process.

Data Needed: Memorandum from LSSARP commenting on the acceptability of LSSA's proposed CAR strategy and approach.

Data Needed: Comments and feedback in LSS Participants' regular status reports to LSSA on reporting/data collection problems.

Objective 1 (cont.)

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant operations and compliance.

Objective 2: Provide compliance assistance commensurate with the need to provide thorough LSS Participant briefing and training while not intervening unnecessarily into the LSS Participants' development of compliance plans.

Objective 2a: Provide complete, accurate, and useable documentation and guidance materials distribution and update mechanisms in a timely manner to all LSS Participants so that processing activities and LSS development are not unduly delayed.

Performance Measure: Timely designated LSS official (DLO) review of and comment on draft guidance materials and distribution and update mechanisms prior to finalization.

Data Needed: Draft guidance materials from LSSA/LSSA contractor.

Data Needed: Comments on draft materials from DLOs within LSSA-established schedule.

Performance Measure: Publication of the Big Book and the Participant Compliance Evaluation Plan guidance for distribution to LSS Participants no later than 60 days prior to deadline for initial LSS Participants' and Future HLW parties' filing of "Part B" of LSS Access Application.

Data Needed: LSSA-established schedule for initial LSS Access Application filings.

Data Needed: LSSA-established schedule for Big Book development and publication.

Data Needed: Distribution and update logs of CAR guidance materials from LSSA contractor.

Objective 2a (cont.)

Performance Measure: Updates of Big Book and Format and Content Guideline for Compliance Evaluation Plans distributed to DLOs within two weeks after LSSA approval.

Data Needed: Distribution and update logs of CAR guidance materials from LSSA Compliance Evaluation contractor.

Objective 2b: Ensure that LSS Participant Compliance Plans are acceptable and effectively implemented to ensure meeting the standards and objectives of the underlying processes (DMI, DMP, and DMS).

Performance Measure: Evidence that the LSS Participants have submitted Compliance Plans and that the Plans have been approved by the LSSA and effectively implemented by the LSS Participants.

Data Needed: Certifications accompanying "Part B" of LSS Access Application regarding LSS Participant intent to prepare and submit a Compliance Plan for LSSA approval.

Data Needed: LSS Participant Compliance Plans from DLOs.

Data Needed: Compliance Plan approval letters from LSSA to LSS Participants.

Data Needed: Certifications, every six months, from each LSS Participant's DLO that Compliance Plans are being effectively implemented.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor of LSS Participants' implementation of their Compliance Plans, including timeliness of implementing LSSA process revisions.

Data Needed: Copies of LSS Participant audit reports on their compliance with their Plans.

Objective 2c: Provide briefing and training programs to ensure thorough understanding of LSS DMI, DMP, and DMS procedures.

Performance Measure: Evidence of thorough and evaluated briefings and training courses for DMI, DMP, and DMS by LSSA contractor.

Objective 2c (cont.)

Data Needed: LSSA contractor-submitted and LSSA-approved briefing and training outlines for the LSS processes.

Data Needed: LSSA feedback and analysis of briefing/training pilot sessions.

Data Needed: Comments and feedback from LSS Participants who have attended briefing and training sessions (including pilot session[s]).

Performance Measure: Evidence of key LSS Participant personnel having been scheduled and having attended briefing and training sessions

Data Needed: Schedule of briefing and training sessions from LSSA contractor, including attendance sheets.

Data Needed: Certifications from DLOs that key LSS Participant personnel (including contractors) have been scheduled for or have attended all briefing and training sessions (or reasonable explanation[s] for not attending).

Data Needed: Comments and feedback from LSS Participants who have attended briefing and training sessions.

Objective 2d: Collect information during the briefings and training to continuously improve the assistance program and the DMI, DMP, and DMS processes.

Performance Measure: Evidence that information during briefing and training has been collected and analyzed by the LSSA for process improvements.

Data Needed: Comments and feedback from LSS Participants who have attended briefing and training sessions.

Data Needed: Report from LSSA briefing/training contractor on completed sessions.

Data Needed: LSSA reports analyzing LSS Participant briefing and training feedback for improving assistance program and the LSS processes.

Objective 2e: Provide ongoing compliance support to LSS Participants, ensuring that the appropriate depth of resources is available in accordance with the Compliance Evaluation Program Plan.

Performance Measure: Evidence that the LSSA submitter support and assistance program is in place and providing effective assistance to LSS Participants according to plan.

Data Needed: LSSA contractor submitter support and assistance program plan, including budget and schedule, reflecting LSSARP comments and LSSA approval.

Data Needed: Monthly reports from LSSA submitter support and assistance contractor describing operations and support provided (e.g., calls received, peak call periods, staffing, problems identified, problem status and resolution, recommendations for program revision) and cost performance (i.e., expenditures vs. budget and operation cost projections).

Data Needed: Monthly reports from DLOs which include comments on use of and problems with submitter support and assistance program.

Data Needed: Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant operations and compliance.

Objective 3: Implement CAR process to ensure effective management and evaluation of the overall LSS process without unnecessarily imposing information supply burdens on LSS Participants.

Objective 3a: Ensure that periodic audits and other reviews of LSS Participant process activities are thorough and conducted expeditiously to facilitate proper LSS development and minimize the impact of any identified process problems.

Performance Measure: Feedback on LSS processes (DMI, DMP, DMS, CAR) and LSS Participant operations provided on a regular basis.

Data Needed: Monthly reports (including production statistics), for the first six months of LSS processing, and every six months thereafter, from LSS Participants on their DMI, DMP, and DMS processing, LSSA assistance program, and participation in compliance audits.

Objective 3a (cont.)

Data Needed: Monthly report from LSSA O&M contractor comparing actual loading statistics with projections, LSS errors detected, and error correction activity.

Data Needed: Monthly report from LSSA submitter assistance contractor on types of problems reported, whether problems were resolved, frequently requested information and suggestions for improvement of the systems and processes.

Data Needed: Monthly reports for the first six months and periodic (minimum every six months) compliance evaluation reports thereafter (including processing problem identification) on LSS Participant operations from LSSA Compliance Evaluation contractor.

Objective 3b: Conduct audits to the degree required to confirm LSS Participants' adherence to their Compliance Plans.

Performance Measure: Evidence of LSS Participants' operating in adherence to their approved Compliance Plans.

Data Needed: Certifications, every six months, from each LSS Participant's DLO that Compliance Plans are being effectively implemented.

Data Needed: Monthly audits for the first six months and periodic audits thereafter by LSSA Compliance Evaluation contractor of LSS Participants' implementation of their Compliance Plans, including timeliness of implementing LSSA process revisions.

Data Needed: Copies of LSS Participant audit reports on their compliance with their Plans.

Objective 4: Ensure that the Commission is kept informed by providing periodic and thorough reports on LSS Participant compliance progress.

Performance Measure: LSS Administrator reports to Commission every six months on LSS Participant compliance status.

Objective 4 (cont.)

Data Needed:	Periodic (minimum every six months) compliance evaluation reports on LSS Participant operations from LSSA Compliance Evaluation contractor.
Data Needed:	Certifications, every six months, from each LSS Participant's DLO that Compliance Plans are being effectively implemented.
Data Needed:	Input and comments from DLOs responding to LSSA evaluations and recommendations regarding their compliance status.

2.3 Information Collection Plan

Information to be collected in this program falls into seven categories:

1. "Compliance Program Plans" provided by LSS Participants.

2. LSS Participants' reports on processing status, including production statistics, problems encountered and problems anticipated.

3. Audit reports from the LSSA Compliance Evaluation contractor on LSS Participant compliance efforts.

4. LSS Participant DLO certifications, including regular six-month certifications and "one time" certifications of actions taken, e.g., LSS Access Application certification on intent to provide a compliance plan.

5. LSSA contractor status reports on activities in their areas of responsibility, e.g., data loading, submitter assistance, Big Book publication and updating, and compliance evaluation.

6. LSSA contractor plans and schedules for programs and activities in their respective areas of responsibility.

7. LSS Participant comments and feedback.

The plan for collecting data in each of these categories follows:

1. "Compliance Program Plans" provided by LSS Participants: The LSSA must notify each LSS Participant of the specific information needed and when it will be needed. The LSSA should provide each Participant with a list of subjects that must be addressed in their compliance plans, as opposed to other information to be submitted separately. For example, subjects that might be required in the compliance plans are: control procedures; internal training program; internal audit or quality control plan; internal controls to prevent fraud; management oversight plan; contractor versus LSS Participant responsibilities; and qualification of key personnel.

2. LSS Participants' reports: The LSSA must determine, but not be limited to, reporting formats and frequencies, substantive report content, and report recipients, and notify each LSS Participant of these requirements.

3. LSSA Compliance Evaluation contractor audit reports: LSSA must obtain auditing assistance from a qualified contractor. A specific audit plan must be developed and implemented, taking into account the schedule for reporting on LSS Participant compliance to the Commission.

4. LSS Participant DLO certifications: The LSS rule requires that LSS Participant DLOs certify that they are in compliance with the rule every six months. The LSSA must establish the date for the first such certification, with each LSS Participant. In addition, the LSSA must identify and define other, one-time "certifications" where DLOs must attest to their accomplishment or commitment to perform certain LSSA requirements.

5. LSSA contractor status reports: LSSA must define reporting information that will be required by contractors to report to the LSSA on a regular basis. Such reports will include status information on the various LSSA training and support programs, as well as LSS processing, loading, and maintenance activities.

6. LSSA contractor plans and schedules: LSSA contractors must develop and provide to the LSSA for approval, their plans, including strategies, approaches, implementation schedules, and budgets, for the various programs and tasks they will perform. These plans and schedules will support LSSA management efforts for meeting their CAR responsibilities.

7. LSS Participant comments and feedback: LSS Participants will be involved in some of the planning and design tasks for compliance assistance programs by reviewing proposed plans, guidance materials, etc., and providing feedback to the LSSA on their effectiveness and impact on Participant compliance activities. Such comments and feedback will serve to benefit the LSS Participants by helping to create effective compliance assistance programs.

2.4 Information / Record Keeping Requirements

The LSSA will retain all records containing information collected or generated under this plan in accordance with Commission records retention and disposal requirements, including any special needs of the HLW licensing process as determined by the PALB, the HLB and the Commission. LSSA contractors will maintain all records relating to their activities in accordance with the terms of their contracts and will notify the LSSA before destroying any records. LSSA will determine which contract records should be retained in accordance with Commission records retention and disposal requirements. LSS Participants will keep process records for a minimum of 1 year after either (1) the completion of the HLW licensing process or (2) the termination of their involvement in the HLW licensing process.

Appendix

Flow Diagrams

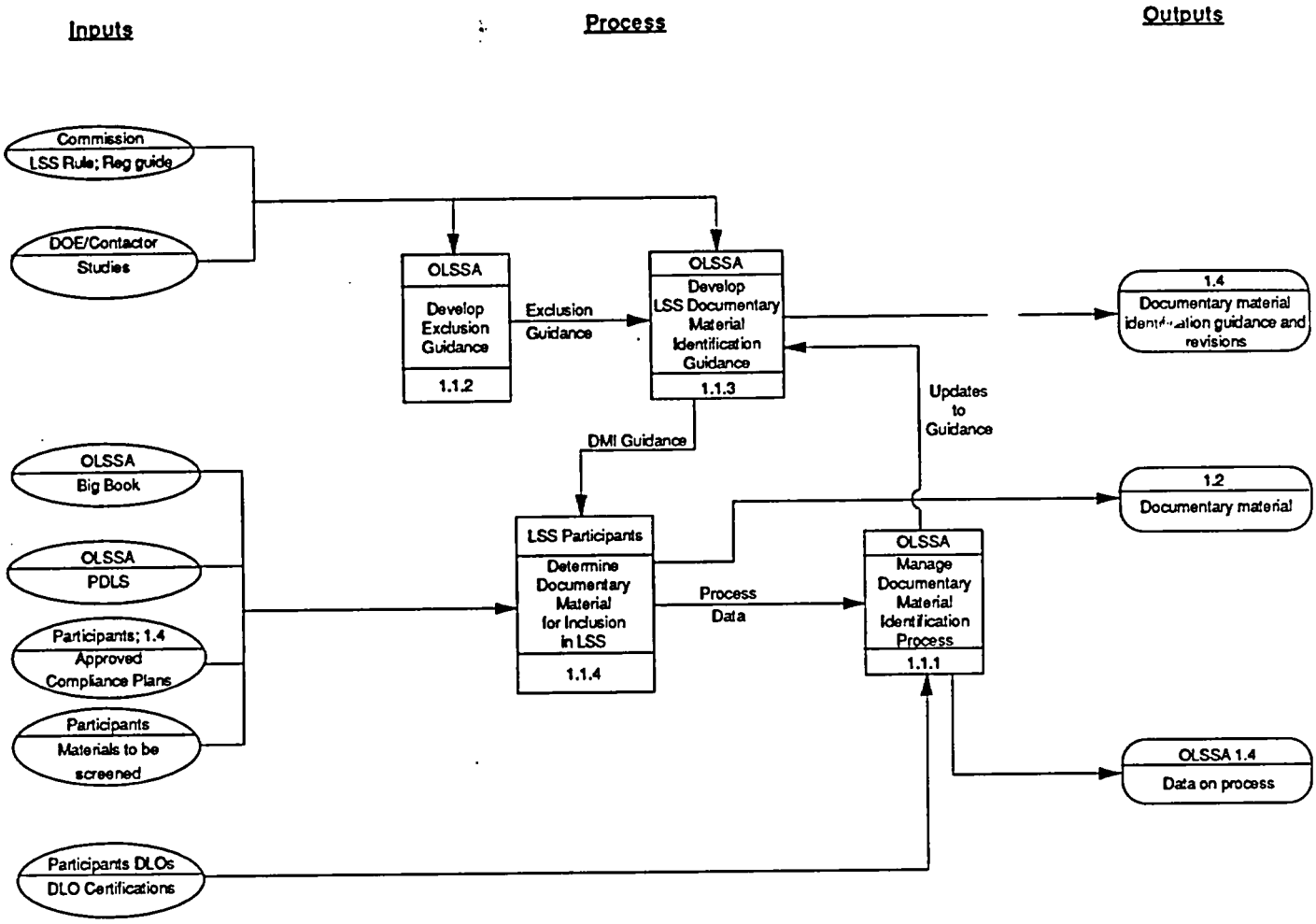
for DMI, DMP, DMS, and CAR

DMI

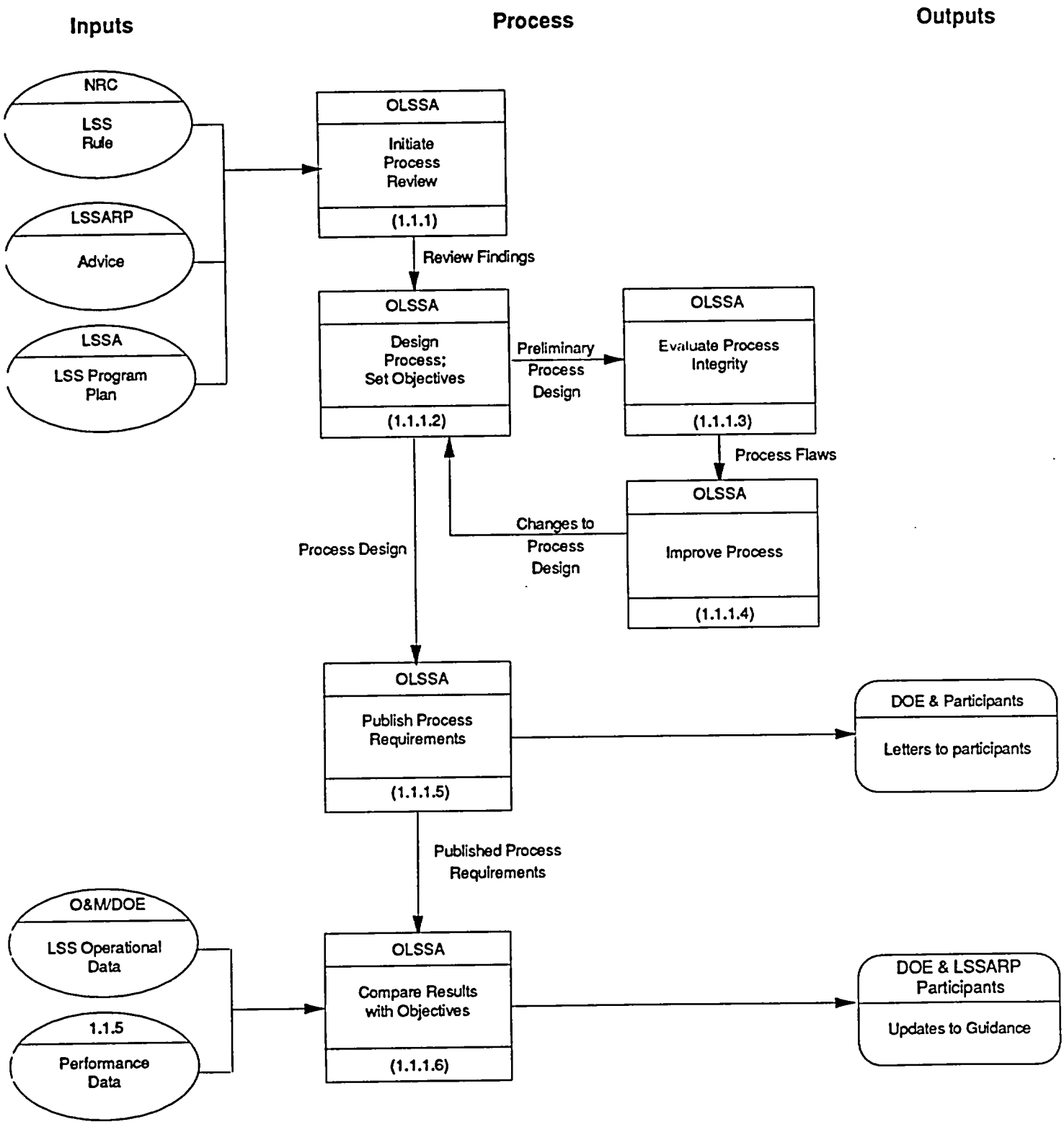
Flow Diagrams

1.0 COMPLIANCE REQUIREMENTS AND EVALUATION

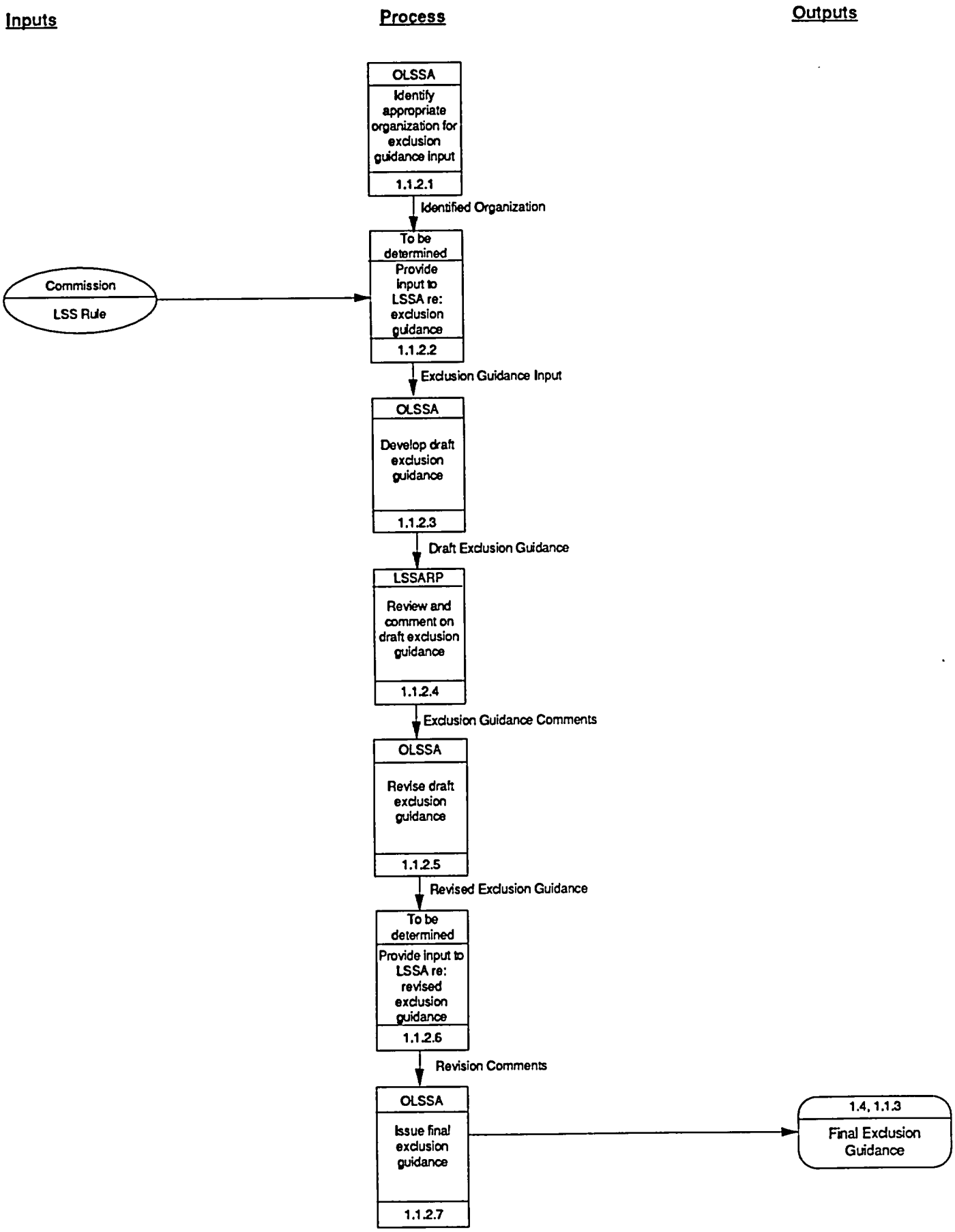
1.1 Documentary Material Identification



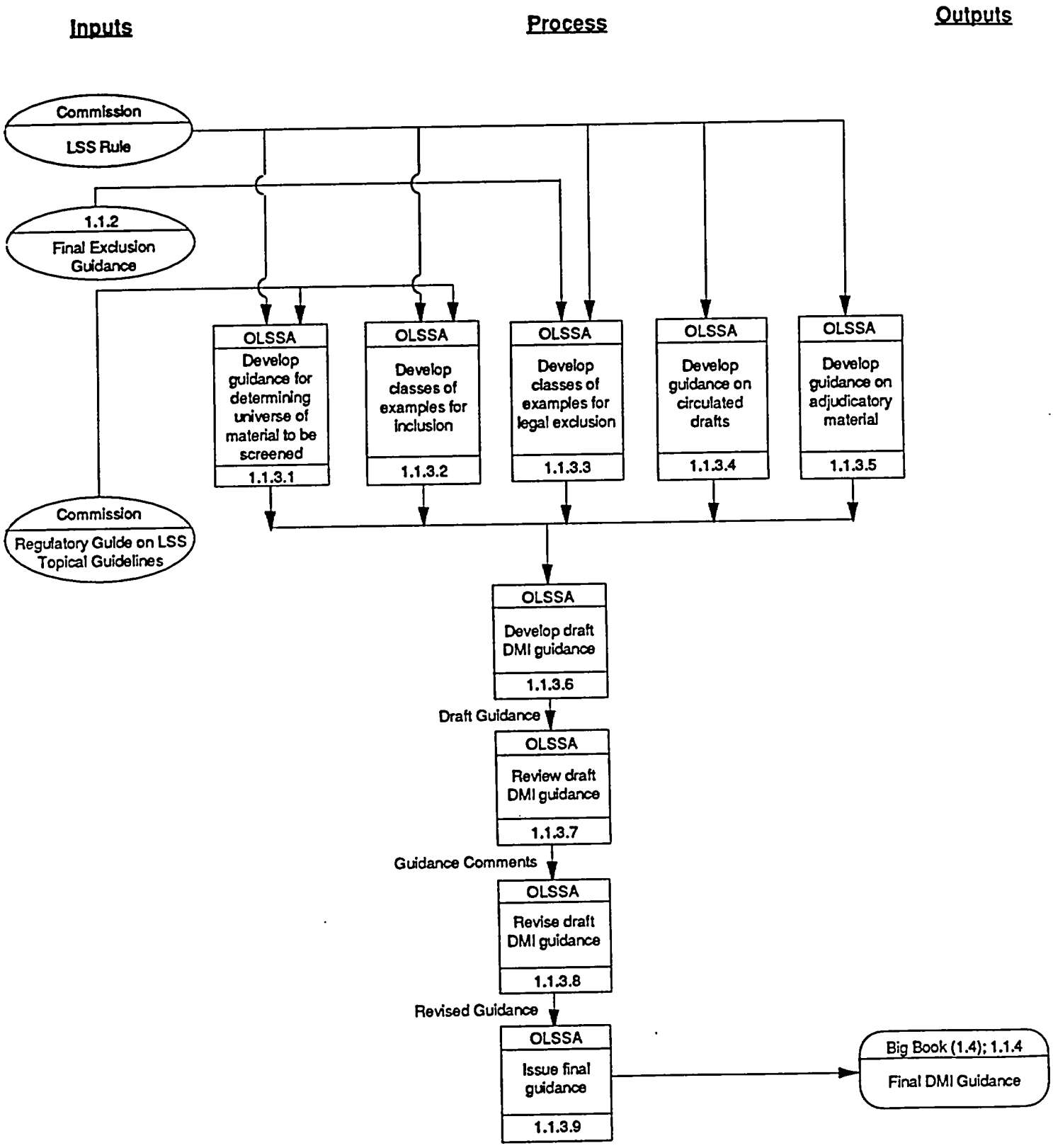
1.1.1 Manage Documentary Material Identification Process



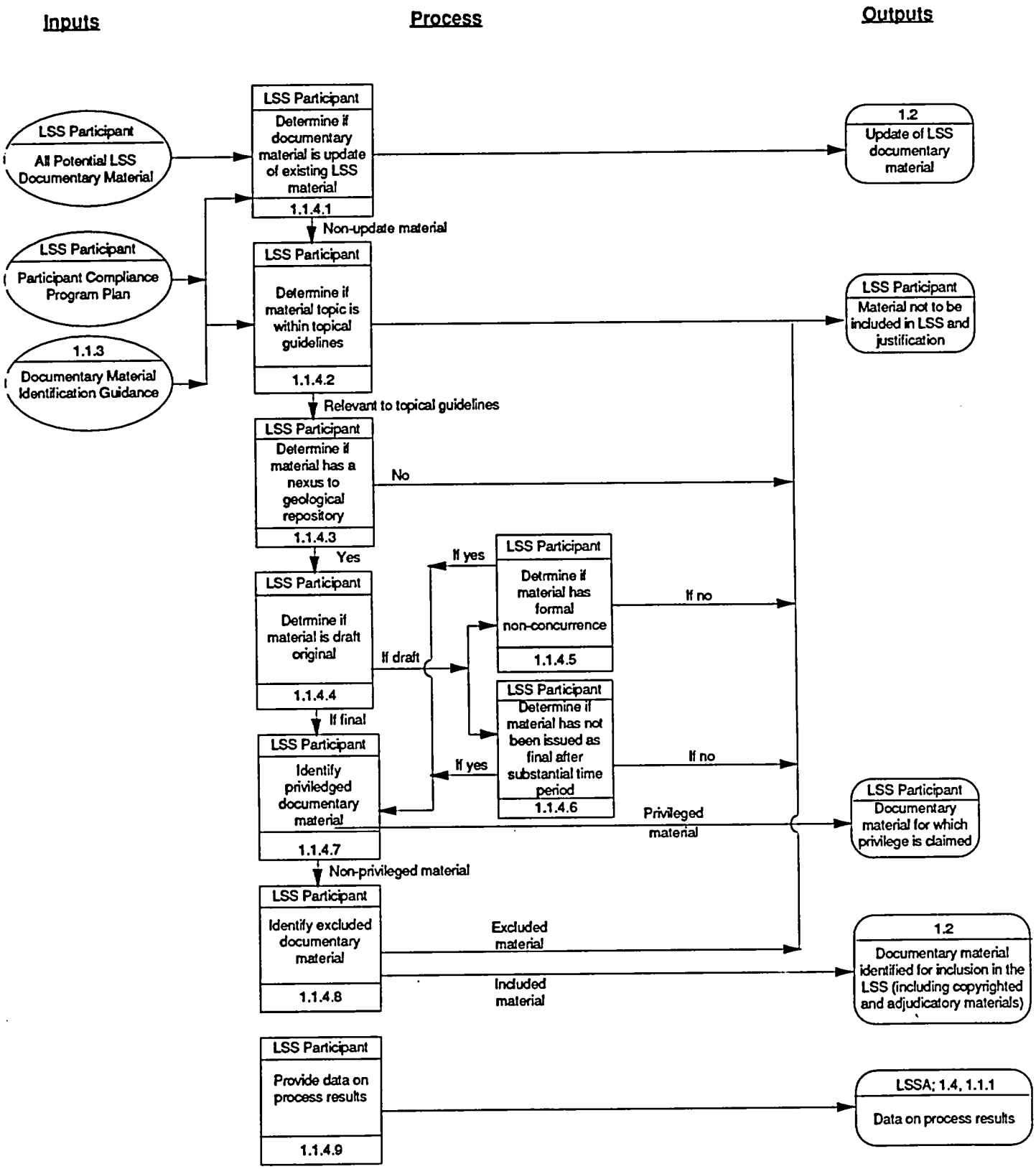
1.1.2 Develop Exclusion Guidelines



1.1.3 Develop Exclusion Guidance



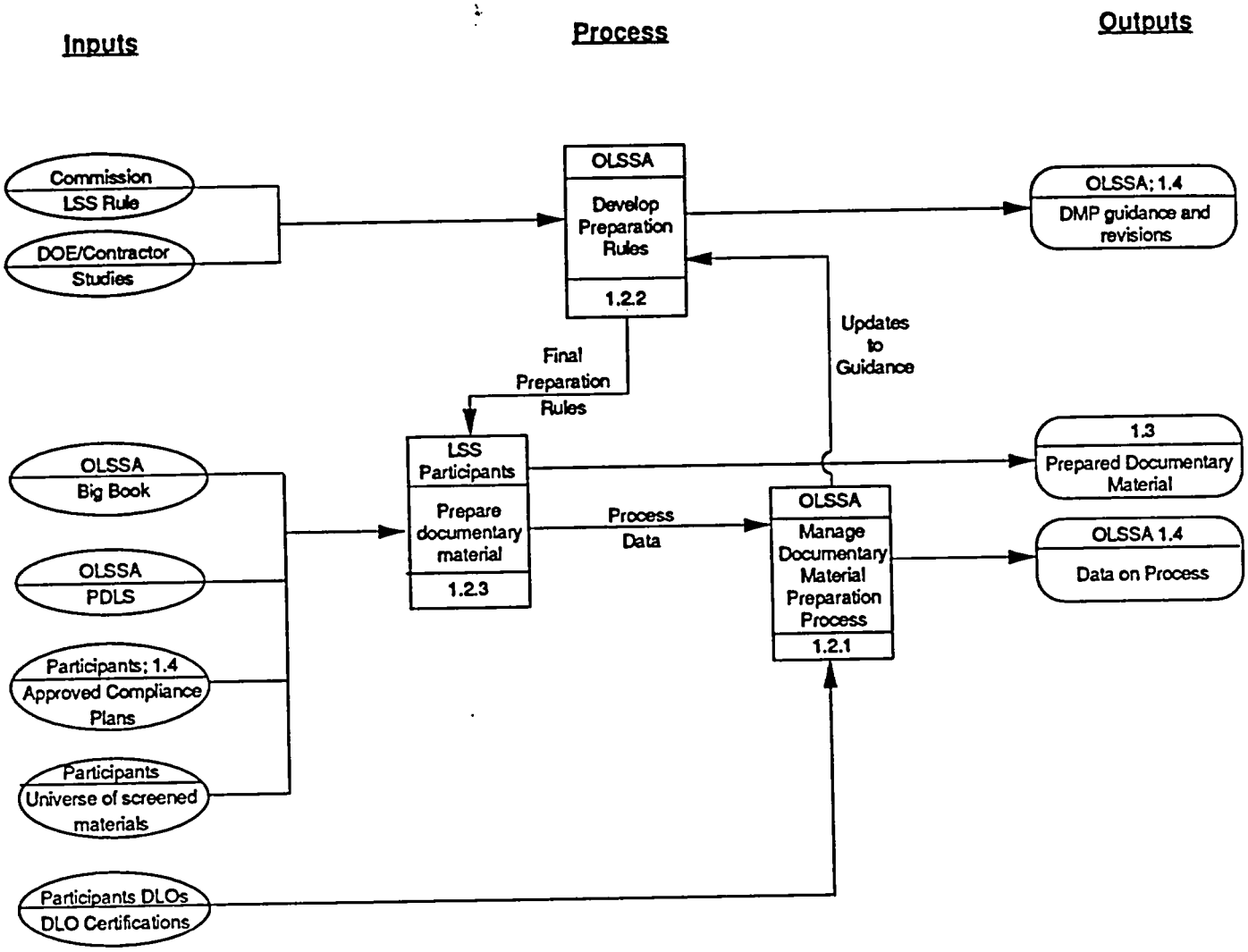
1.1.4 Determine Documentary Material for Inclusion in LSS



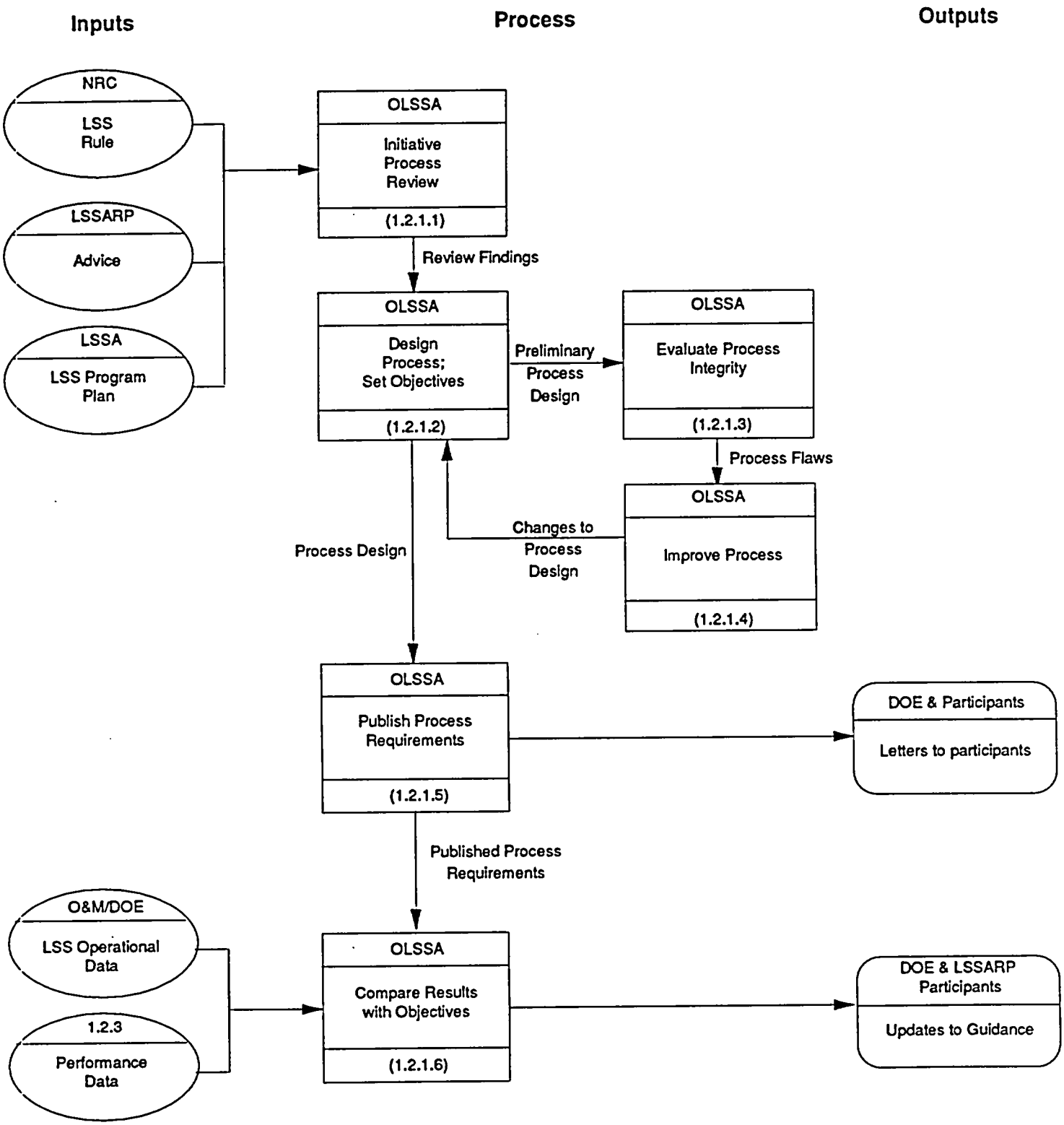
DMP

Flow Diagrams

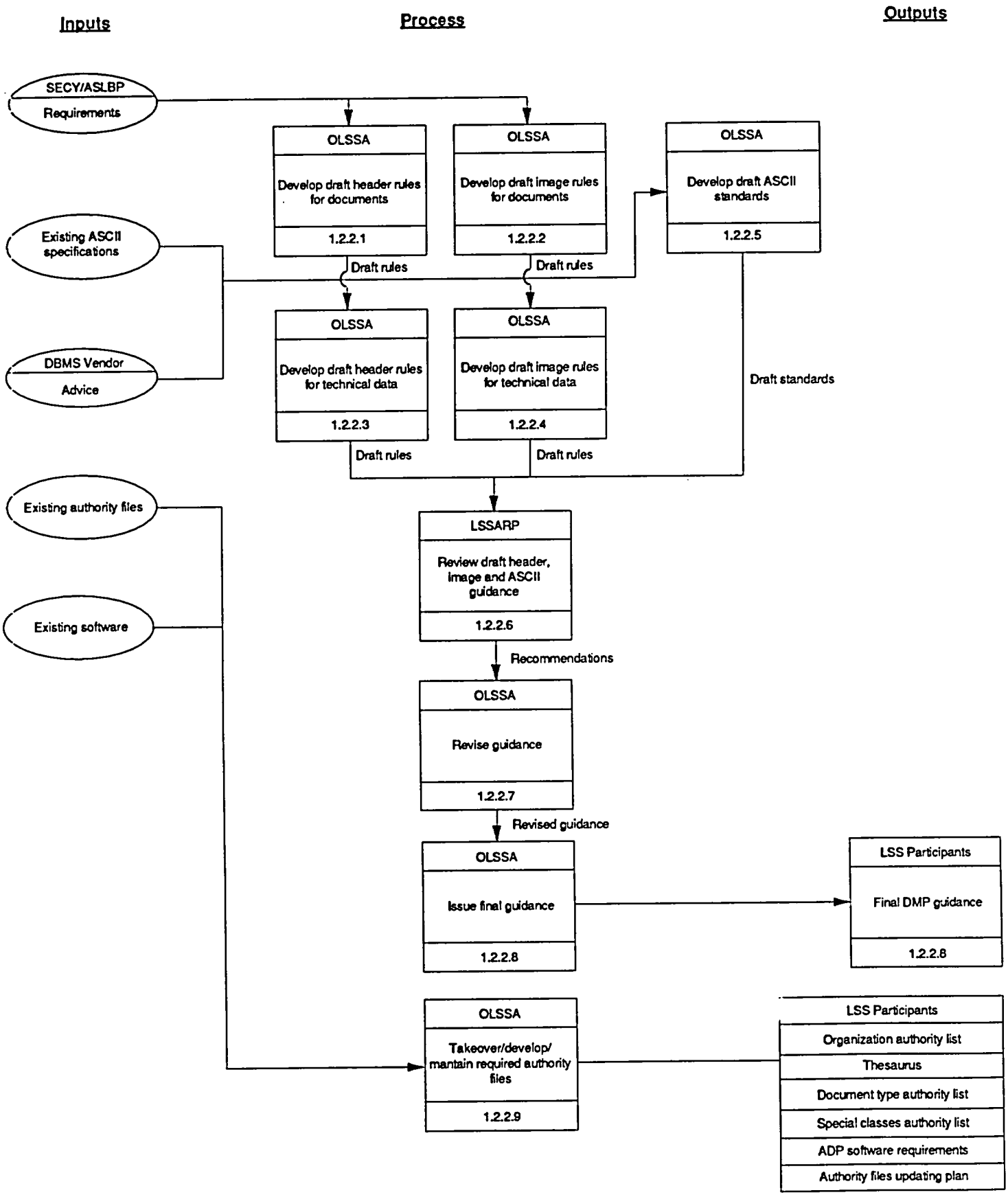
1.2 Documentary Material Preparation



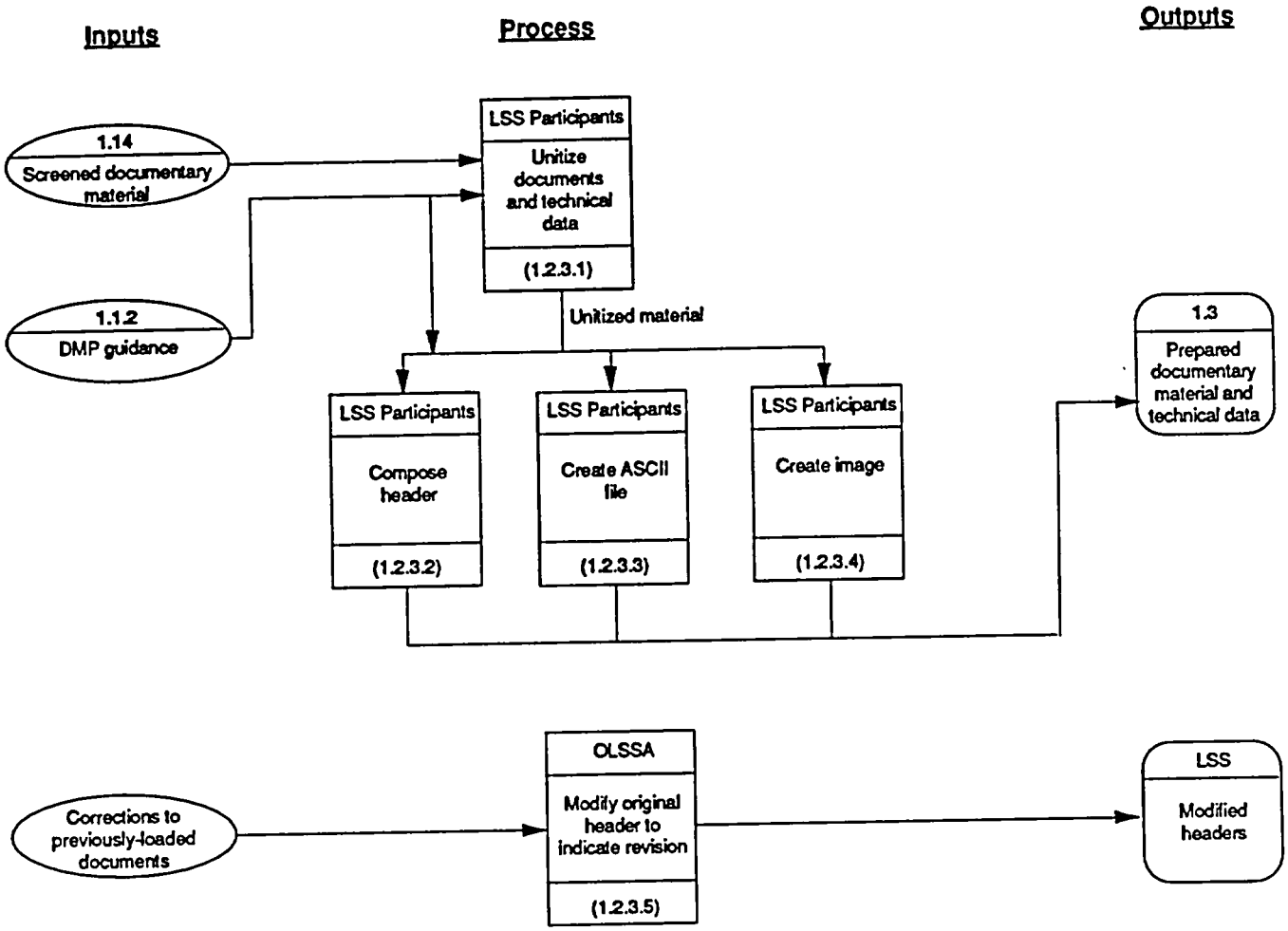
1.2.1 Manage Documentary Material Preparation Process



1.2.2 Develop Preparation Rules



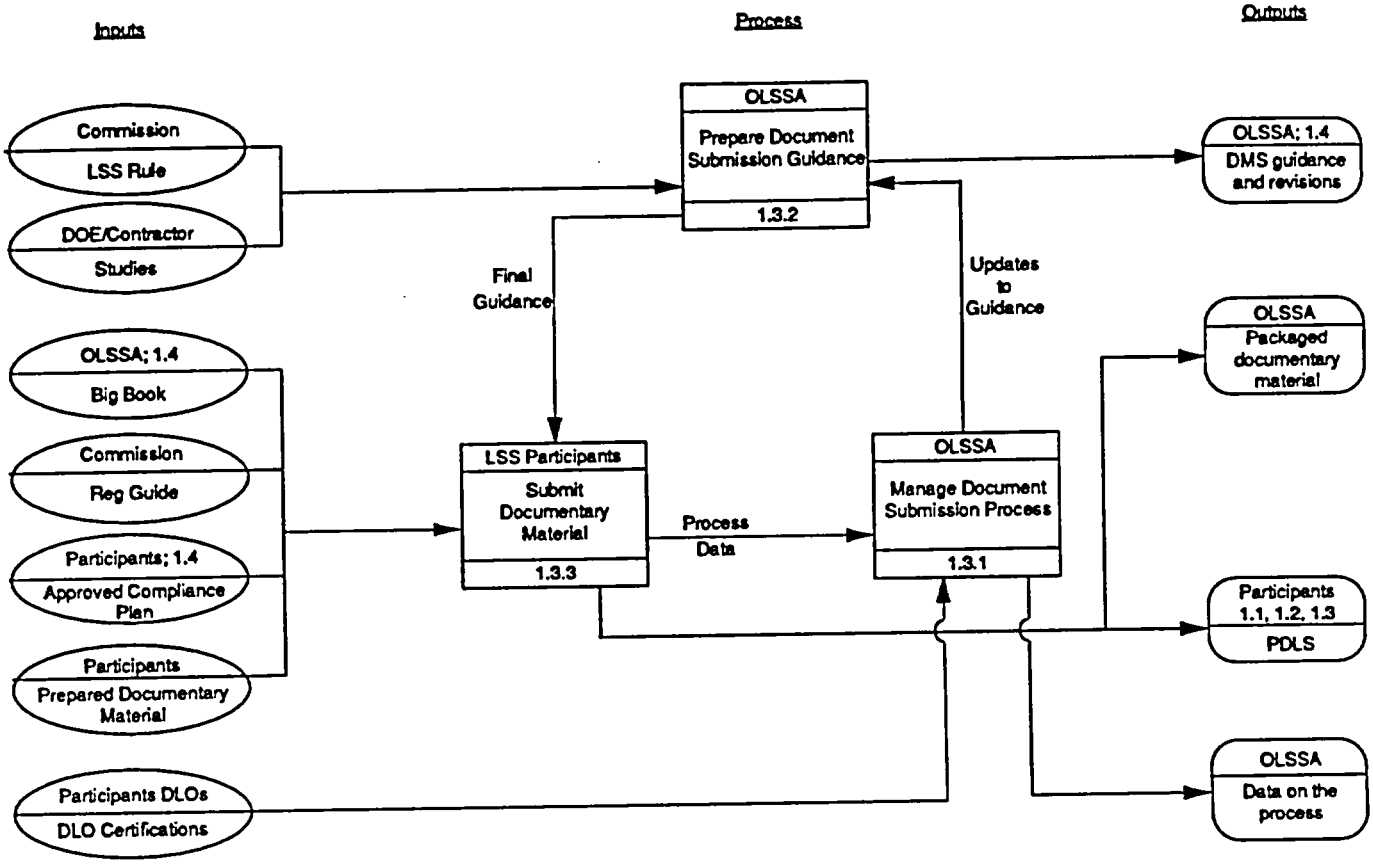
1.2.3 Prepare Documentary Material



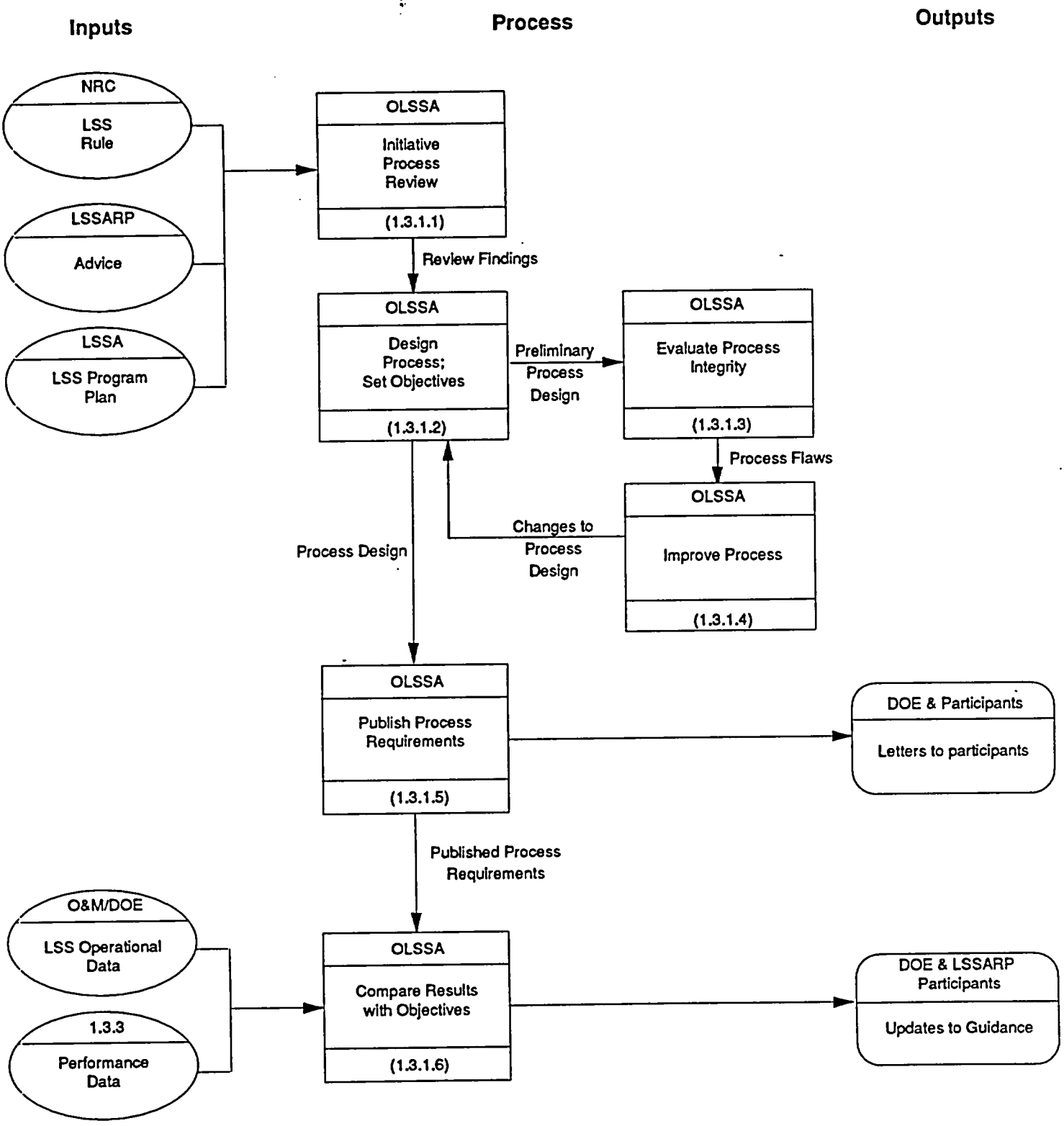
DMS

Flow Diagrams

1.3 Document Submission

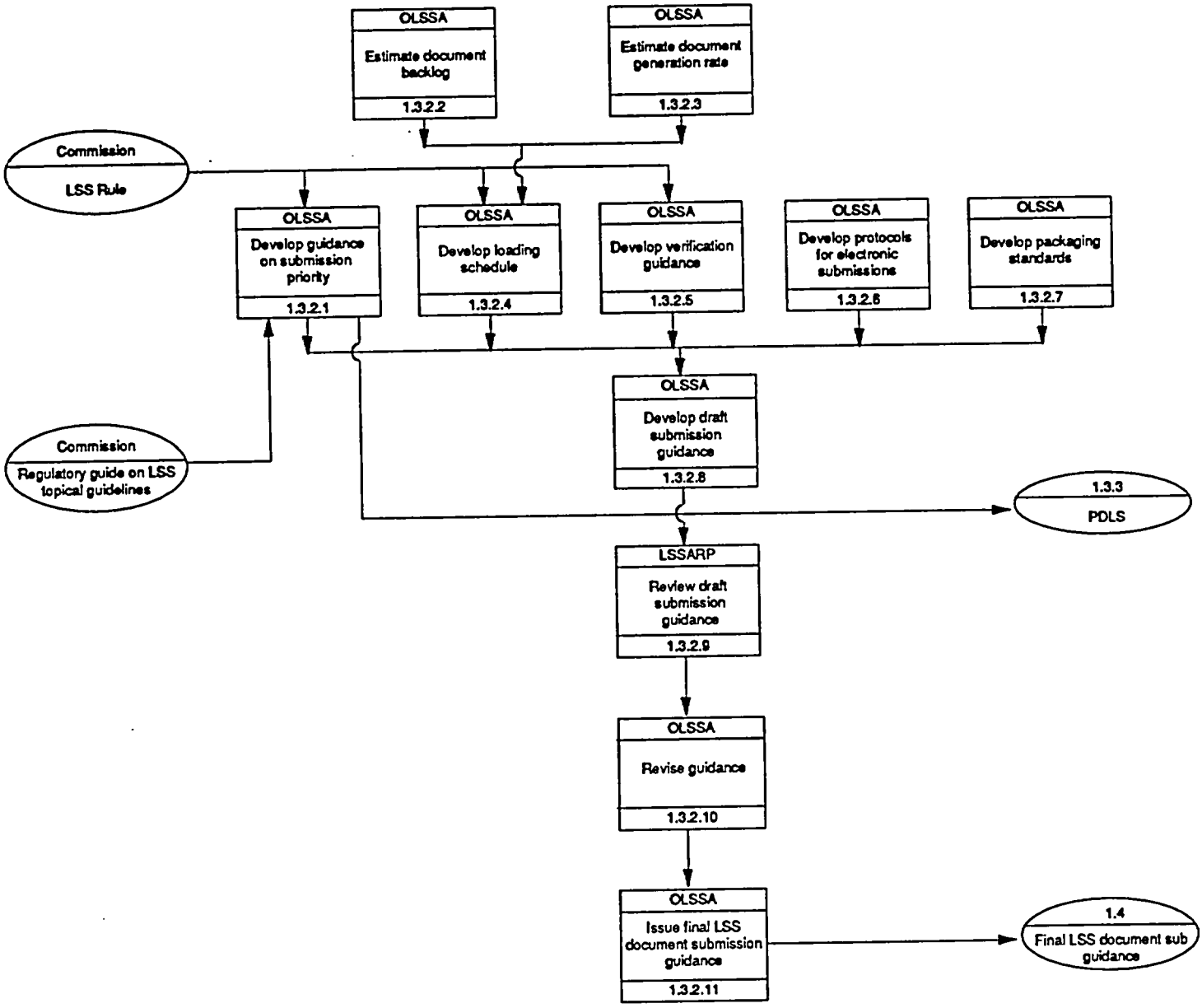


1.3.1 Manage Documentary Material Submission Process

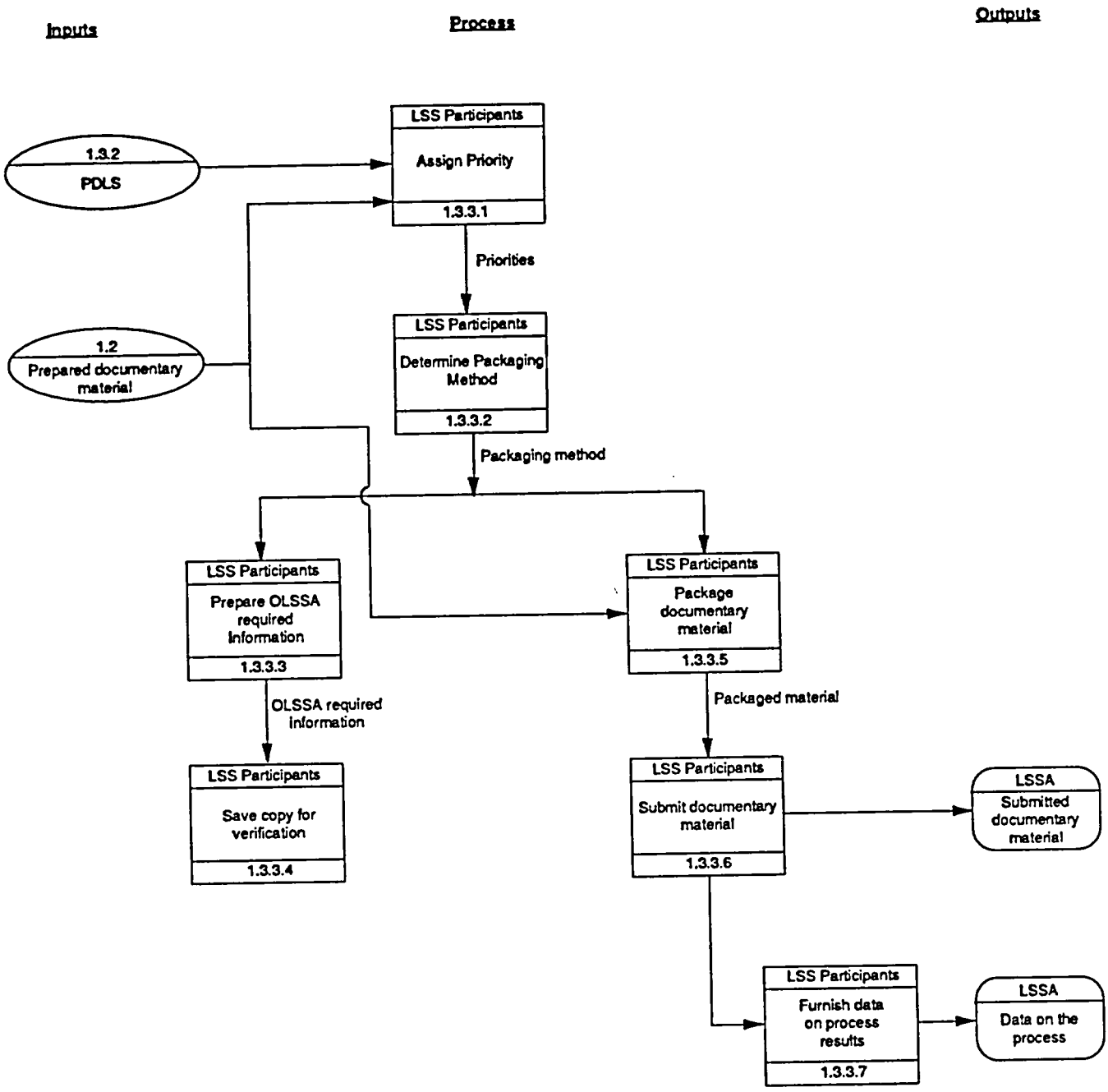


1.3.2 Prepare Documentary Material Submission Guidance

Inputs **Process** **Outputs**



1.3.3 Submit Documentary Material

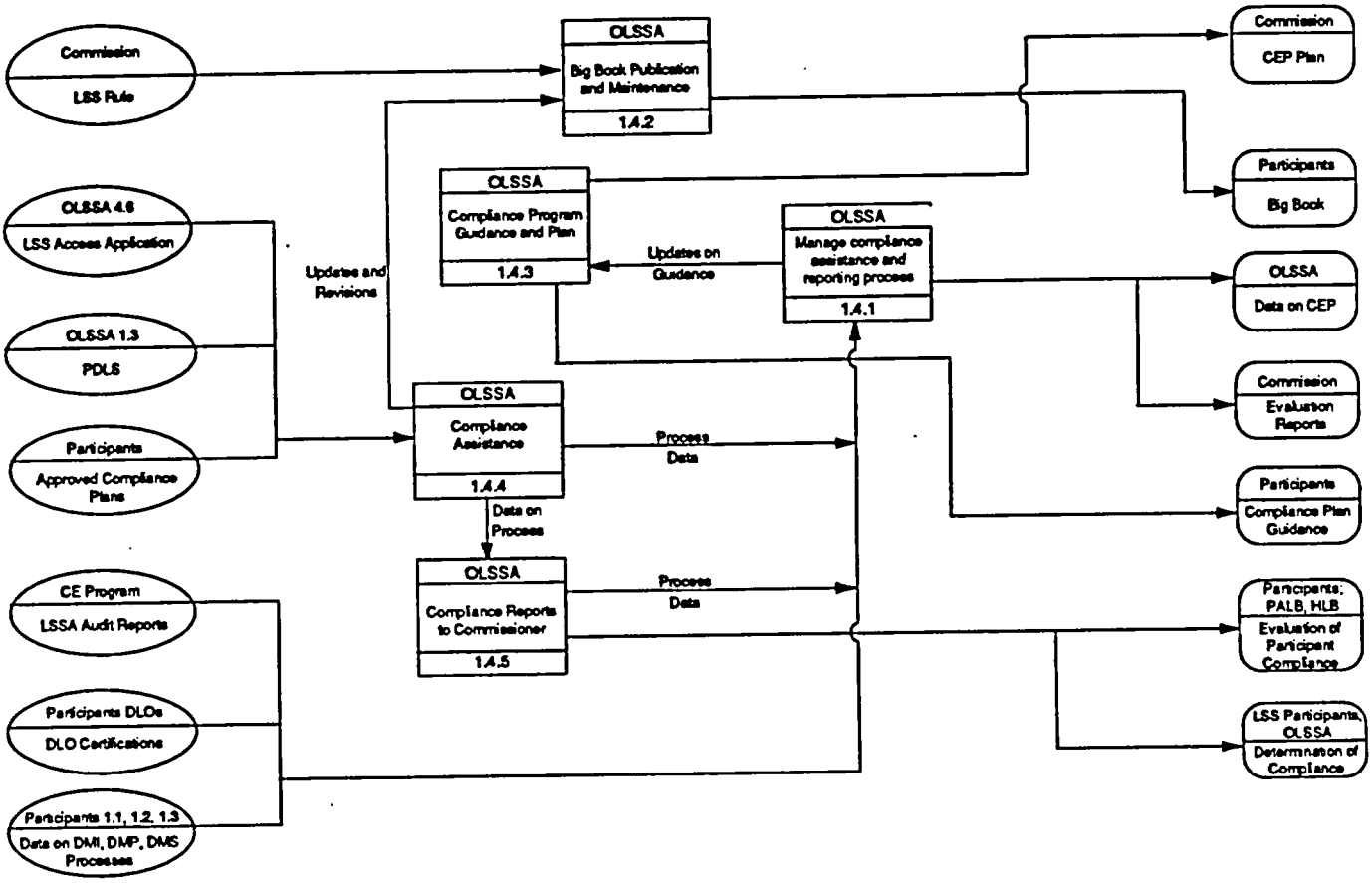


CAR

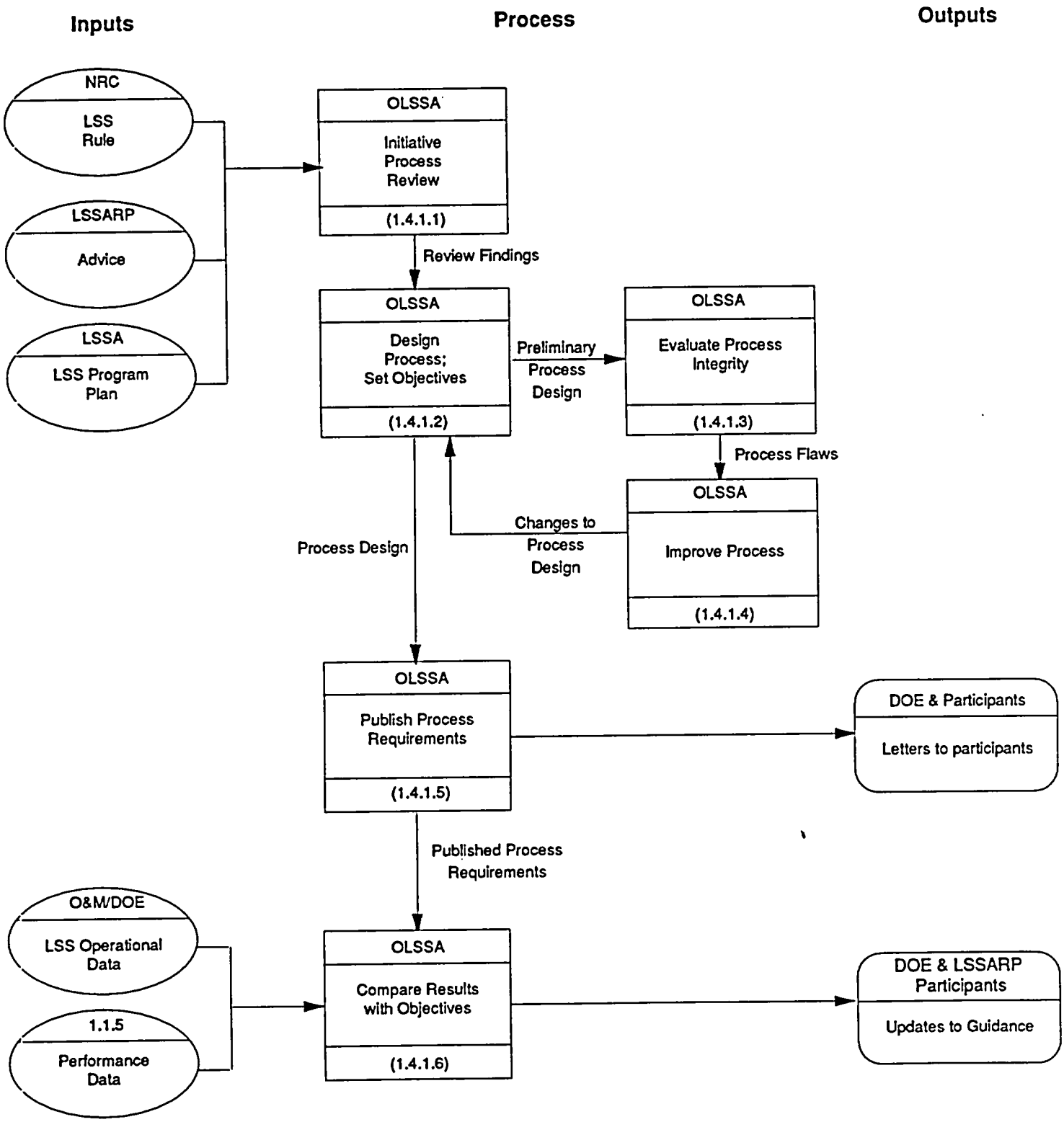
Flow Diagrams

1.4 Compliance Assistance and Reporting

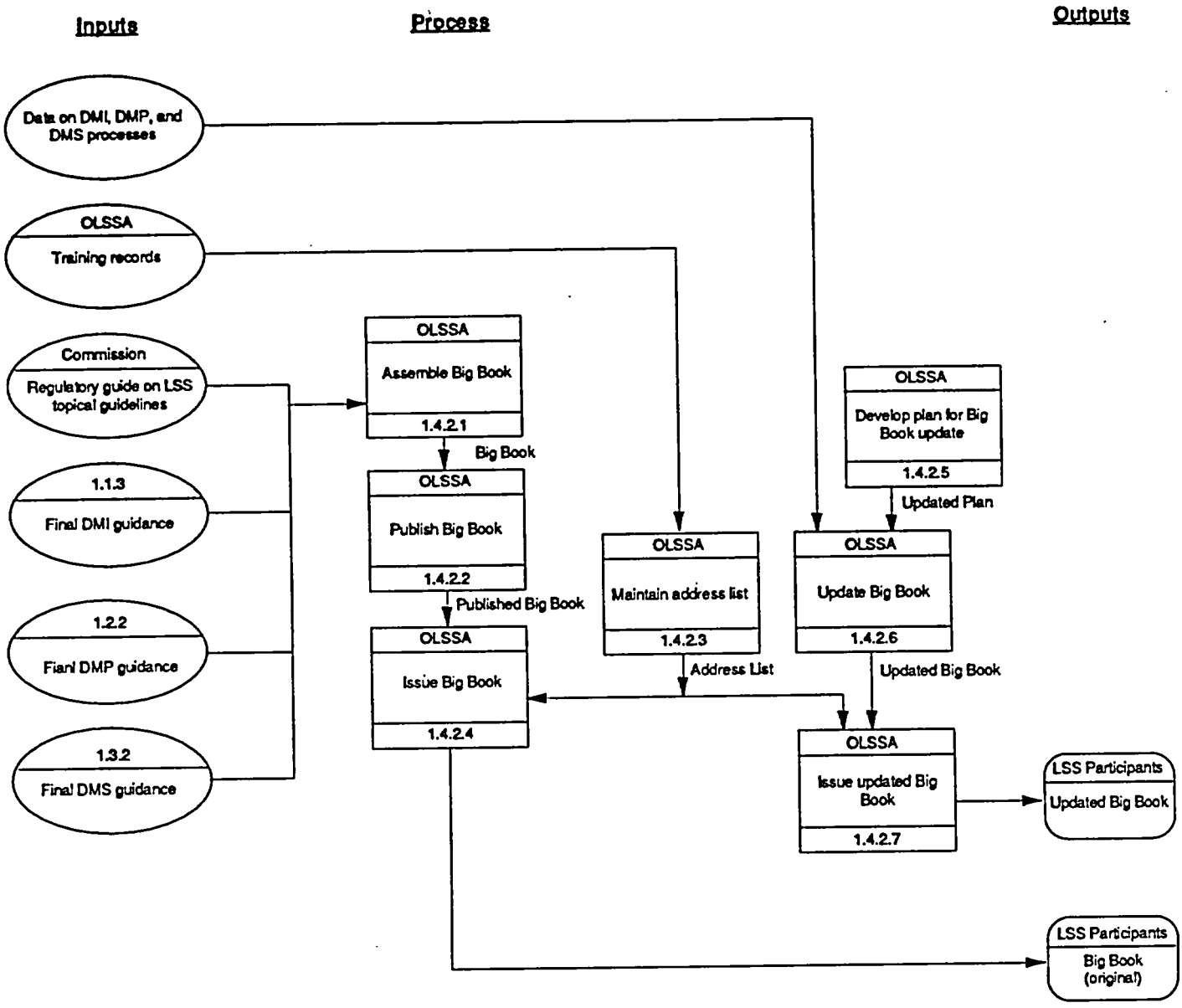
Inputs **Process** **Outputs**



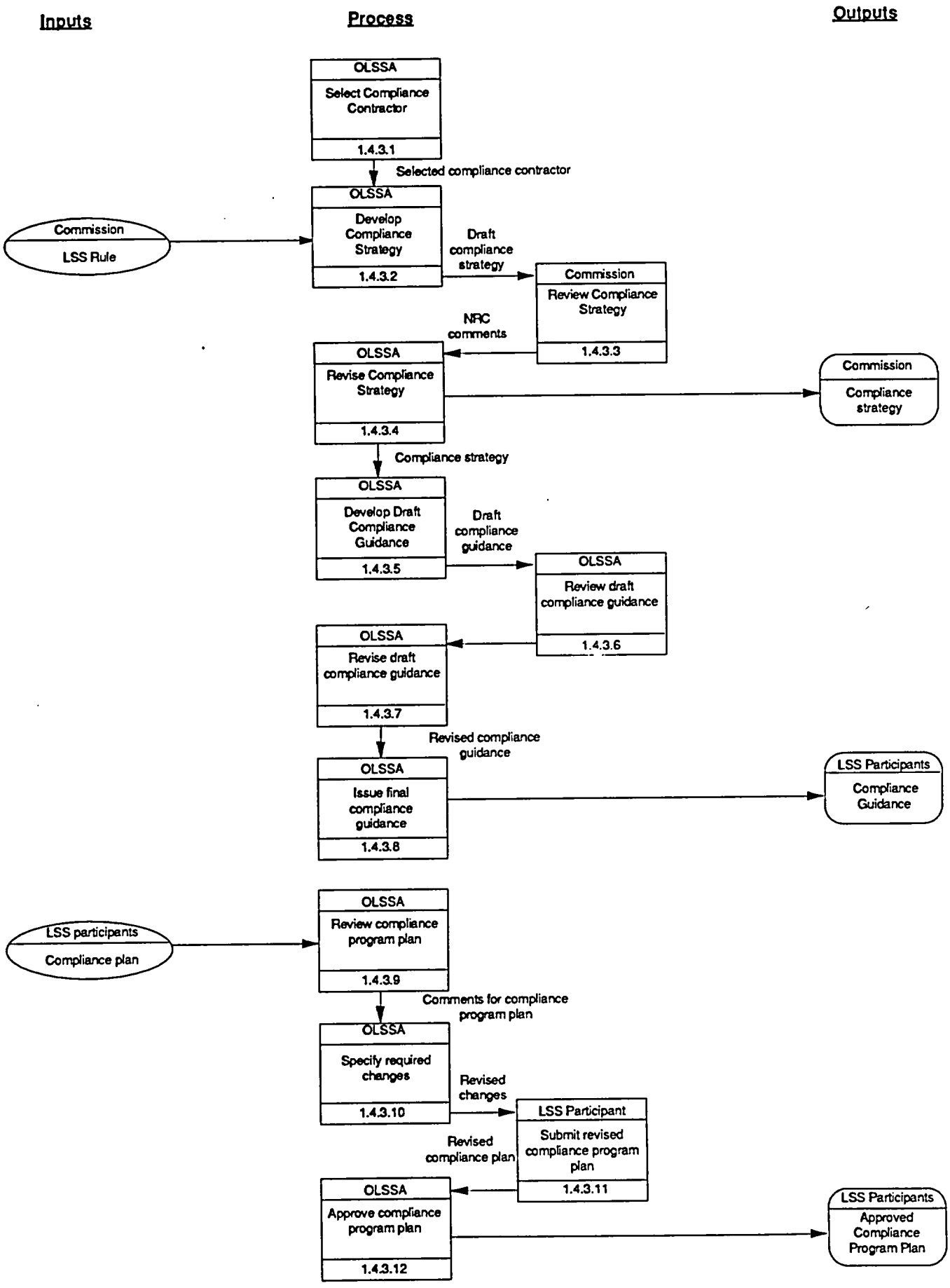
1.4.1 Manage Compliance Assistance and Reporting



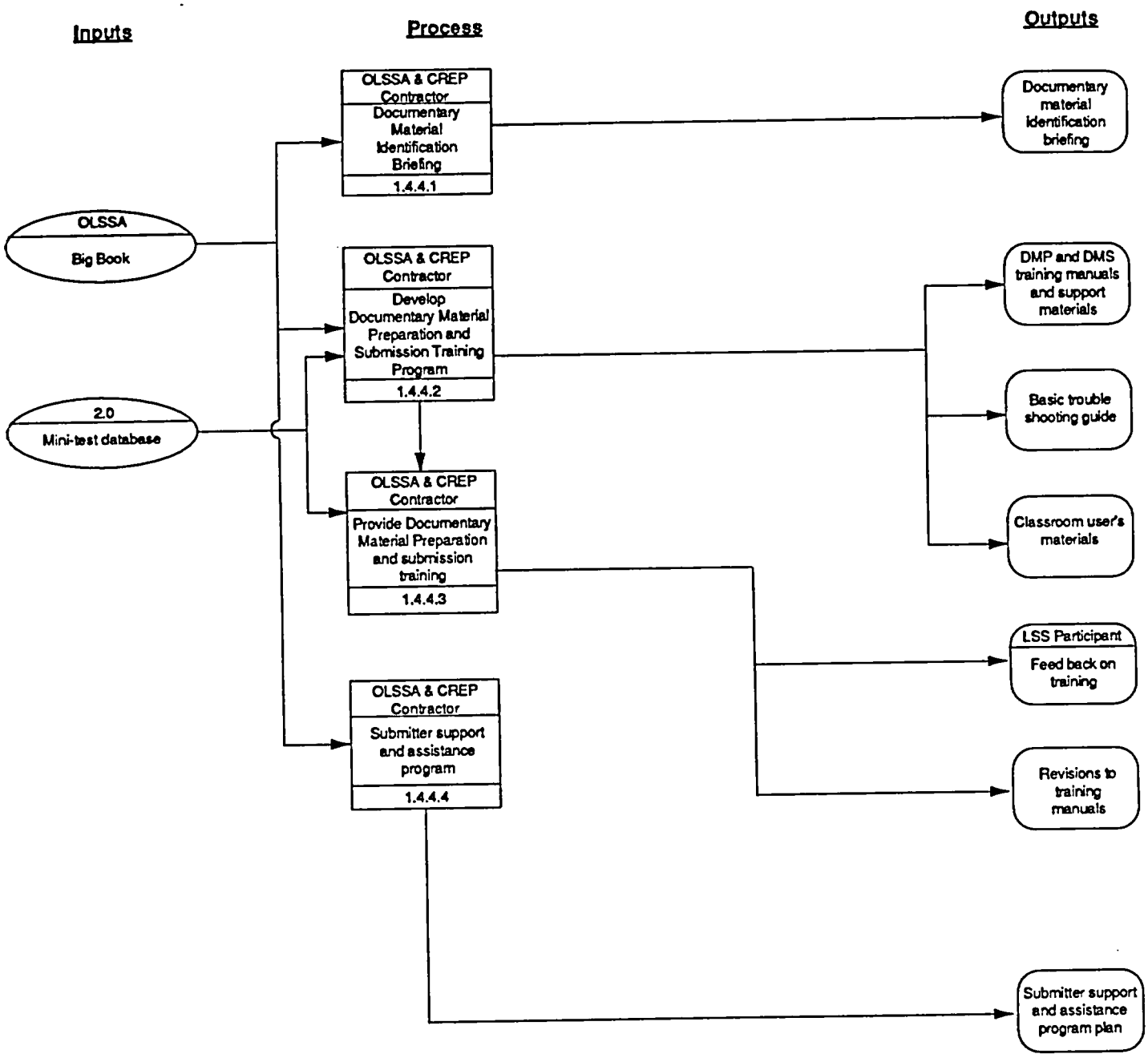
1.4.2 Big Book Publication and Maintenance



1.4.3 Compliance Program Guidance and Plan Review



1.4.4 Compliance Assistance



1.4.5 Compliance Reports to Commisioners