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**LICENSING REVIEWS AND DESIGN RECONCILIATION**

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**ABSTRACT**

Certified packaging designs are defined by the packaging certification or licensing drawings, which are usually part of the formal safety analysis and which are referenced in the certificate of compliance granted by the cognizant regulatory authority. The packaging fleet, on the other hand, is typically fabricated using a separate drawing set, which contains much more detail than does the licensing drawings. The same is true for specifications, procedures, and tests: delineated in simplified form in the safety analysis, but containing more detail for actual site use. Document reviews must be performed to ensure that the drawings, specifications, spare parts lists, and operating manuals are consistent with the certification safety documents.

Because the USNRC does not grant change authority to the certificate holder, the packagings must strictly conform to the licensed packaging drawings. However, to successfully fabricate a packaging, both more detail and a tighter control of tolerances is typically needed. Thus, a separate set of drawings is created, typically denoted as fabrication, or shop drawings. But it is important that the fabrication drawings and related documents remain in compliance with the licensing drawings. Thus the need for a formal reconciliation of the two. This paper compares the two types of documents, and discusses the performance and timing of licensing reconciliation reviews. It closes with several case studies of issues that could arise from incomplete or ill-timed reviews.

**INTRODUCTION**

The approval of a radioactive material (RAM) packaging by a competent authority is based in part on the description of the packaging's design. The drawings are typically provided with the Safety Analysis Report (SAR) and define the packaging in sufficient detail to support the safety analysis. Fabrication of packagings is typically governed by a separate, and much more detailed set of shop drawings. Similarly, material or process specifications, test procedures, and operating procedures may be provided in the SAR which contain less detail than the corresponding documents used for fabrication and operation of the packagings. Thus there exists in most cases two parallel sets of packaging-related documents: licensing documents and fabrication documents. This paper will discuss the importance of keeping these document sets consistent with each other, and offers guidelines and case studies.

## RAM PACKAGING DOCUMENTS

The set of drawings that is supplied with the SAR for approval by a competent authority is used to define the design and to form a basis for evaluating its safety and compliance with the applicable regulations. In most jurisdictions, the SAR drawings constitute a condition of approval in the Certificate of Compliance (CoC), and the packagings in use must comply fully with the drawings, and independent authority to alter the design is not granted. The expected content of SAR drawings is spelled out by the United States Nuclear Regulatory Commission (USNRC) in Section 3.1, *General Guidance*, of NUREG/CR-5502 [1]: “The drawings should specify those details of the package design *which affect its evaluation under 10 CFR 71*” (emphasis added). Thus, the SAR drawing should include only a subset of the full amount of information needed to fabricate a packaging.

Fabrication drawings, on the other hand, will be as detailed as necessary in order to instruct the fabrication shop to produce the required packaging hardware. The set of fabrication drawings will typically consist of significantly more sheets than the SAR drawing set, and may include subsets such as forging drawings, rough machining drawings, lead pour details, etc. Many of these details are not relevant to the safety evaluation. As further defined in Section 3.1 of [1],

The technical content appropriate for drawings submitted in a package application may differ substantially from that of other drawings routinely prepared for design and fabrication...Detailed fabrication (shop) drawings, however, may provide excessive detail that is not appropriate as a condition of approval.

In other words, any detail included on the SAR drawings will necessarily become a condition of approval, regardless whether it is relevant to the safety evaluation or not. Consequently, in most cases, two separate and parallel drawing sets must be maintained for a packaging design. This is also true for other aspects of packaging fabrication, maintenance, and use, including fabrication procedures, purchasing specifications, operating and maintenance procedures. Table 1 lists some of the documents used in packaging development and use and depicts their correspondence between safety evaluations and fabrication or operation.

This principle also holds true in cases where some change authority is granted, such as for Type A or lower-grade packagings. In that case, changes to the design may be made subsequent to qualification, but a documented evaluation must show that the changed configuration is fully compliant with the applicable regulations.

## DRAWING RECONCILIATION

It should be clear by this point that, in order to adhere to the conditions of the CoC, the fabrication and operation documents must be fully consistent with the safety documents. This can only be ensured by a robust licensing reconciliation program. Licensing reconciliation is a two-step process:

1. Ensure that the fabrication drawings fully implement all of the features and requirements of the SAR drawings, and
2. Ensure that the fabrication drawings do not permit any variations not explicitly permitted on the SAR drawings.

(From this point on, the term ‘fabrication drawing’ will stand for all documents, such as fabrication drawings, operating manuals, purchasing specifications, etc., that are required to

fully implement the licensing documents.) For example, a SAR drawing might require a closure bolt to be nickel plated. The first step is to verify that the fabrication drawing includes such a requirement, to at least the level of detail specified in the SAR drawing. The second step is to verify that no optional platings are permitted by the fabrication drawing (unless permitted by the SAR drawing). Once the two drawings have been reconciled, the fabrication drawing fully (and restrictively) implements the SAR drawing.

However, licensing activity is not yet complete. While SAR drawings normally cannot be altered except by formal license amendment, fabrication drawings can be changed at any time. Changes to the fabrication drawings often become necessary during fabrication activities in order to account for lessons learned, such as unexpected fabrication difficulties. Further, fabrication nonconformances commonly occur which are immaterial to the utility or safety of the packaging, and therefore may be acceptable. Therefore, after a formal reconciliation between the SAR and fabrication drawings has occurred, further licensing reviews must be performed and documented when processing fabrication drawing changes or during the evaluation of nonconformances. In this way, any fabrication which is found to be in compliance with the fabrication documents, including drawings, specifications, change notices, and approved nonconformances, will by definition be in compliance with the CoC.

## **RECONCILIATION GUIDELINES**

The first principle to keep in mind is to keep the SAR drawing as simple as possible, consistent with its purpose. According to [1], the SAR drawing should include only the details that are relevant to the safety evaluation. For example, it is typically unnecessary to include such fabrication details as true position requirements, chamfer sizes, most surface finishes, dimensions that do not support a clear understanding of the design or support a safety analysis, etc. Surface finish should be specified only where it is of importance to containment, such as in sealing areas. Tolerances should be specified somewhat larger than those on the fabrication drawing, consistent with safety. In some cases, such as in sealing areas, tolerances must be specified the same, or very nearly the same, as is expected to be achievable on the fabrication, due to the critical nature of such features. On the same principle, the SAR's operating or maintenance procedures must not be over-specified.

Next, it is important to ensure that the SAR drawing and other licensing documents are correct, since all subsequent activities must conform to them. Errors will not only affect licensing, but have a significant cascade into fabrication and beyond.

It is a good idea to delay formal reconciliation of the licensing and fabrication documents until they need to be used. A formal, documented reconciliation process is necessary to ensure completeness. However, if this formal process is performed too early, before the SAR drawings or fabrication drawings are mature, it will need to be repeated. If done too late, expensive errors could occur during actual fabrication. Therefore, reconciliation should consist, during development, of continuous, informal checking, realizing that the two sets of drawings do not need always to be in perfect agreement but that serious deviations are signs of future trouble. Then, when ready to begin actual fabrication, the formal reconciliation may be performed, using released drawings. This is a fitting closure to the development process and “puts a stake in the ground”, establishing a point in time when the drawings and other documents are in full agreement.

Once fabrication begins, ensure that the quality procedures in use require formal licensing reviews of all drawing changes (of either the SAR or fabrication drawings) and of all nonconformances. In this way, the formal agreement established previously can be maintained.

## CASE STUDIES

**Case Study No. 1: The importance of informal reconciliations.** A large lead-shielded transport cask was initially designed with a 25-mm inner shell thickness. An expensive stainless steel alloy, having a long manufacturing lead-time, was chosen for this component. Calculations were then performed which showed the minimum thickness should be 32 mm. The SAR was developed using this information. In parallel, the fabrication drawings were developed using the original concept drawings having a thickness of only 25 mm. The inconsistency was overlooked for the time being, and to shorten the schedule, the long lead-time materials were placed on order with a material supplier. This order included the inner shell using the incorrect 25-mm thickness. After several months passed, the full set of SAR drawings and fabrication drawings were completed and released, and a licensing reconciliation was performed. At this time, the inconsistency between the SAR drawing and the fabrication drawing was discovered. The fabrication drawing was easily corrected, but the long-lead material order had to be cancelled and several months of schedule was lost.

*Lesson learned:* Even though the formal SAR – fabrication drawing reconciliation was properly performed on released drawings, the designer failed to informally keep the safety analysis and fabrication drawings in basic agreement. No CoC violation took place, but a significant business loss occurred.

**Case Study No. 2: The importance of attention to detail in formal reconciliations.** A containment O-ring seal was specified on the SAR drawing to be made from fluoroelastomer material. The fabrication drawing incorrectly identified the material as EPDM. A formal reconciliation was performed, but this discrepancy was overlooked. Because the properties of the two materials only differ under extreme conditions, all of the acceptance and preshipment leakage rate tests were passed. However, the CoC was violated. In addition, the EPDM material might not perform as expected under hypothetical accident fire conditions.

*Lesson learned:* Errors caused by a lack of correspondence between the SAR and fabrication drawings may not be physically evident under normal conditions of operation, yet still present a risk to the public. Licensing reconciliations must be performed with strict attention to detail.

**Case Study No. 3: One way in which an apparently good reconciliation may not be good enough.** A containment lid weldment outer ring was designed to require a specific final thickness. This was done on the SAR drawing by specifying the outer diameter of the ring along with the ring's thickness,  $t$ . On the fabrication drawing, the ring was dimensioned using the outer and inner diameters of the ring. The thickness  $t$  was not shown, but could be derived. See Figure 1. A reconciliation was performed and found that, since the two approaches amounted to the same thing, the drawings were acceptable. However, during fabrication activities, the inner diameter of the ring did not meet the fabrication tolerances. A nonconformance report was processed which determined that, since the inner diameter was not specified on the SAR drawing, the deviation was acceptable. The fact that the deviation in inner diameter caused the ring thickness  $t$  to exceed the SAR drawing tolerance was overlooked.

*Lesson learned:* Even though a reconciliation had been performed, it was still possible that a violation of the SAR drawing could occur because the SAR and fabrication drawings had a different basis for the ring thickness. The fabrication drawing was *capable* of producing the correct SAR drawing dimension, but it did not *guarantee* it. Ensure that each SAR drawing dimension is explicitly called out on the fabrication drawing, and not merely derived, so that it can be properly considered during the review of any potential nonconformance reports. Alternately, create a fabrication procedure that ensures the measurement and recording of each SAR drawing dimension.

## **CONCLUSIONS**

The receipt of a CoC from the regulatory authority does not mean that all licensing activities are completed. If the package is to be properly fabricated, attention must be paid to the reconciliation between the SAR and corresponding fabrication drawings. These drawings necessarily differ due to the differing needs of the safety evaluation and fabrication. But in order to avoid a violation of the CoC, the fabricated packaging must fully conform to the licensed configuration and other requirements of the CoC. A well-timed and accurate drawing reconciliation is required, followed by careful control of drawing changes and nonconformances.

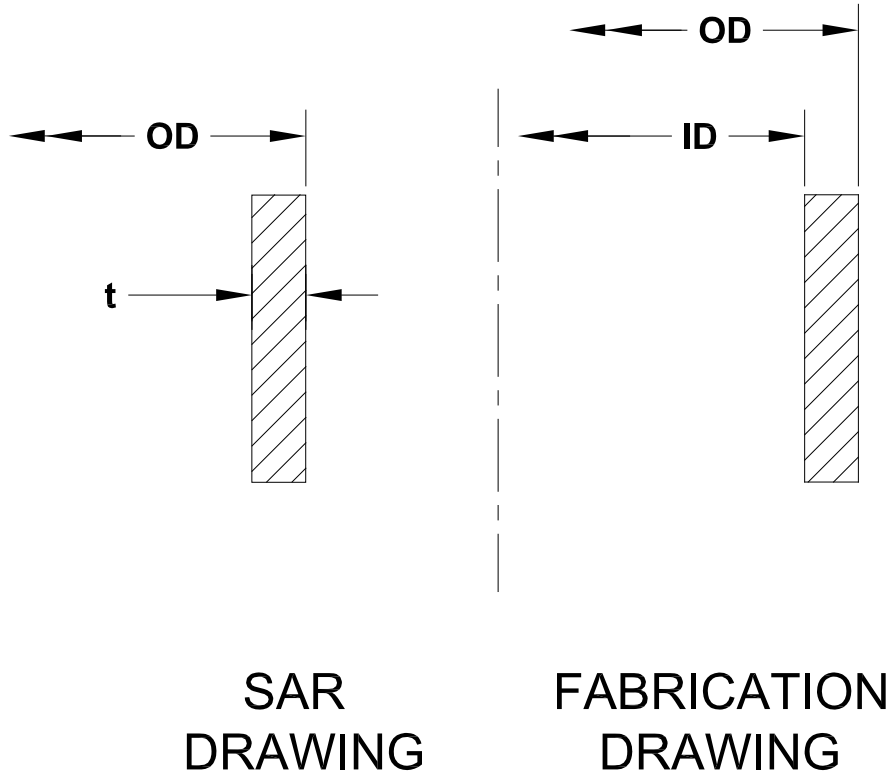
## **REFERENCES**

1. *Engineering Drawings for 10 CFR 71 Package Approvals*, NUREG/CR-5502, U.S. Nuclear Regulatory Commission, May 1998.
2. *Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material*, Regulatory Guide 7.9, U.S. Nuclear Regulatory Commission, March 2005.

**Table 1. Comparison of Licensing and Fabrication/Operation Documents**

<b>Safety Document*</b>	<b>Fabrication Document</b>
<p>SAR Drawings (Reg Guide 7.9 Chapter 1)</p>	<p>Fabrication Drawings Fabrication Procedures Welding Qualifications Spare Parts Lists</p>
<p>Acceptance and Maintenance Procedures (Reg Guide 7.9 Chapter 8)</p>	<p>Procurement Specifications Processing Specifications Acceptance Tests Maintenance Procedures</p>
<p>Package Operations (Reg Guide 7.9 Chapter 7)</p>	<p>Site Operating Procedures</p>

\*The safety documents listed are standard chapters of the safety analysis report (SAR) as defined in [2].



**Figure 1. Case Study No. 3 Example: Lid Weldment Outer Ring**