



121 North Henry Street  
Alexandria, VA 22314-2903  
T: 703 739 9543 F: 703 739 9488  
arsa@arsa.org www.arsa.org

April 29, 2016

DELIVERED VIA EMAIL *lorelei.peter@faa.gov*

ORIGINAL DELIVERED BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED 70142120000020082344

---

Lorelei Peter  
Assistant Chief Counsel for Regulations  
FAA National Headquarters  
Orville Wright Bldg. (FOB10A)  
800 Independence Ave., SW  
Washington, DC 20591-0001

**RE: Reconsideration of Legal Interpretation dated January 27, 2014**

Dear Ms. Peter:

The Aeronautical Repair Station Association (ARSA) respectfully requests that the Federal Aviation Administration (FAA) reconsider the above-referenced interpretation, which states that second- and third-tier documents are incorporated by reference (IBR'd) in airworthiness directives (AD).<sup>1</sup> The agency's position conflates multiple elements of the Administrative Procedure Act (APA)<sup>2</sup> and threatens aviation safety by creating significant uncertainty in AD compliance.

**Original Request for Clarification and FAA Response.**

On August 28, 2013, ARSA requested a legal interpretation confirming that the following language from [Order 8110.103A](#) was incorrect:

**Question:** The AD requires that I accomplish specific instructions in a [Service Bulletin (SB)]. Those instructions require actions from a manual, and the manual requires actions from a standard practice manual. My operating procedure differs from the standard practice manual. Do I need an [alternative method of compliance (AMOC)] to keep using my operating procedure?

**Answer:** Yes. You must accomplish the specific instructions in the SB specified in the AD, *including any second- or third-tier documents that are required to complete the action(s)*.<sup>3</sup>

ARSA argued that second- and third-tier references—which have not been properly IBR'd in the parent AD or published in the Federal Register—are not binding or enforceable. More

---

<sup>1</sup> ARSA's initial request for a legal interpretation and the FAA's response are enclosed for your convenience.

<sup>2</sup> [5 U.S.C. §§ 551 et seq.](#)

<sup>3</sup> [FAA Order 8110.103A, CHG 1, App. A, Question \(f\) \(June 30, 2011\) \(emphasis added\).](#)

RE: Reconsideration of Legal Interpretation dated January 27, 2014.

specifically, ARSA contended that the guidance violated the FAA's own regulations,<sup>4</sup> the APA's publication requirement,<sup>5</sup> and the regulations implementing the APA.<sup>6</sup>

On January 27, 2014, the FAA rejected ARSA's request. The agency tacitly admitted the APA required multi-tiered references to be published in the Federal Register, but that they were nevertheless binding and enforceable because the public had "actual notice of the referenced documents." The FAA explained that second- and third-tier references were "typically" documents that most operators and maintenance providers use to perform work. According to the FAA's interpretation, since repair stations are "generally required" to have these documents under 14 C.F.R. § [145.109\(d\)](#), maintenance providers have actual notice of the documents' existence.

The FAA then revised [Order 8110.117](#) to clarify guidance for referring to other documents in an SB that is IBR'd in an AD.<sup>7</sup> The revision acknowledges that the FAA must obtain approval from the Office of the Federal Register (OFR) for each document IBR'd in an AD; however, those not properly incorporated are enforceable if the regulated party has actual notice.<sup>8</sup>

**The FAA Must Publish Multi-Tiered References or Obtain OFR Approval to Specifically Incorporate Each and Every Unpublished Document by Reference.**

The APA mandates federal agencies "separately state and currently publish in the *Federal Register*...substantive rules of general applicability."<sup>9</sup> Substantive rules "impose mandatory obligations" and must therefore be published in the *Federal Register* to "keep outside interests informed of the agency's requirements."<sup>10</sup> As such, substantive rules must be published in their entirety, or, in the alternative, any unpublished material must be "reasonably available" **and** "incorporated by reference...with the approval of the Director of the Federal Register."<sup>11</sup> Only if an agency satisfies **both** requirements will an unpublished document be "deemed published" under the APA.<sup>12</sup>

Airworthiness Directives are substantive rules because they "specify instructions you must carry out, conditions and limitations you must comply with, and any actions you must take to resolve an unsafe condition."<sup>13</sup> As such, an AD must be published in its entirety. Likewise, if

---

<sup>4</sup> See generally [14 C.F.R. part 39](#).

<sup>5</sup> [5 U.S.C. § 552\(a\)\(1\)](#).

<sup>6</sup> [1 C.F.R. part 51](#).

<sup>7</sup> [FAA Order 8110.117A, Service Bulletins Related to Airworthiness Directives, para. 5\(a\) \(June 18, 2014\)](#).

<sup>8</sup> [FAA Order 8110.117A, para. 11\(c\)](#).

<sup>9</sup> [5 U.S.C. § 522\(a\)\(1\)](#) (emphasis added).

<sup>10</sup> [Appalachian Power Co. v. Train, 566 F.2d 451, 455 \(4th Cir. 1977\) \(internal citations omitted\)](#).

<sup>11</sup> [5 U.S.C. § 552\(a\)\(1\)](#).

<sup>12</sup> [5 U.S.C. § 552\(a\)\(1\)](#); see also [1 C.F.R. part 51](#). The agency claimed that the APA's implementing regulations in [1 C.F.R. part 51](#) were irrelevant because "that part only contains the requirement for obtaining approval [for incorporation by reference]." However, the agency's argument conflates the "reasonable availability" of a document, a requirement for IBR, with the concept of actual notice. Failure to see the relevance of these regulations leads to the inability to enforce mandates in multi-tiered references.

<sup>13</sup> [14 C.F.R. § 39.11](#).

RE: Reconsideration of Legal Interpretation dated January 27, 2014.

the FAA intends for an unpublished component maintenance or standard practice manual referenced in a SB—which itself is properly IBR'd—to be binding and enforceable, the second- or third-tier manual reference is a substantive rule. The FAA must either publish each document, or demonstrate that it is reasonably available **and** obtain approval from the Director of the Federal Register to specifically incorporate it by reference into the parent AD. Current FAA practice and guidance address neither requirement, thus rendering the requirements in multi-tiered references unenforceable.

**Actual Notice is Not Established by the Mere Availability of Unpublished Documents.**

The FAA rightly noted in its response to ARSA that an unpublished regulation which is required to be published may be enforced against a person with “actual and timely notice of the terms thereof.”<sup>14</sup> The agency stresses that multi-tiered references in ADs are to documents that are reasonably available to maintenance providers.<sup>15</sup> In other words, because maintenance providers “typically” use, or are “generally required” to have, the unpublished documents, they have *actual notice* of the requirements contained therein. However, federal courts have soundly rejected similar claims by other agencies attempting to enforce requirements in unpublished documents.

For instance, in [Appalachian Power Co. v. Train](#), the Fourth Circuit held that a 275-page “development document” detailing a standard the Environmental Protection Agency (EPA) would use to approve water intake systems was unenforceable for want of publication.<sup>16</sup> The EPA asserted that the development document was “reasonably available,” and therefore, regulated entities had “actual notice” of the standard.<sup>17</sup> The court rejected the argument, noting that the APA “sharply distinguishes between the concepts of actual notice and reasonable availability.”<sup>18</sup>

Indeed, “actual notice” is a substitute for publication while the “reasonable availability” of an unpublished document is one of two conjunctive requirements for IBR.<sup>19</sup> The mere availability of a document “does not suffice to establish that regulated entities had actual notice of which materials in the development document were intended to be incorporated.”<sup>20</sup> At most, the EPA could establish that regulated entities had the ability to acquire actual

---

<sup>14</sup> [5 U.S.C. § 552\(a\)\(1\)](#).

<sup>15</sup> Ironically, the FAA relies on the “general availability” of maintenance documents while it continues to struggle to define a manufacturer’s obligation under [14 C.F.R. § 21.50\(b\)](#) to “make available” maintenance information that is essential to the continued airworthiness of a product. See, e.g., [Legal Interpretation to Sarah MacLeod \(Aug. 9, 2012\)](#) (noting difficulties in defining the scope of information that must be made available under [§ 21.50\(b\)](#) and opining that manufacturers could make maintenance information “effectively *unavailable* by charging an exorbitant fee”) (emphasis in original).

<sup>16</sup> [Appalachian Power Co. v. Train](#), 566 F.2d 451 (4th Cir. 1977).

<sup>17</sup> [Id.](#) at 456.

<sup>18</sup> [Id.](#)

<sup>19</sup> [Id.](#)

<sup>20</sup> [Id.](#)

RE: Reconsideration of Legal Interpretation dated January 27, 2014.

notice; however, the ability to acquire notice and actual notice are not the same.<sup>21</sup> Such is the case here.

The FAA cannot establish that maintenance providers have actual notice of multi-tiered references simply because they are allegedly “reasonably available.” Even if the agency could establish the documents’ availability, it fails to demonstrate maintenance providers have actual notice of the exact materials or portions of the documents mandated by the parent AD. Service Bulletins and standard practice manuals are voluminous and contain numerous references to other documents, which in turn reference additional documents. As the Fourth Circuit noted in *Appalachian Power*, mere knowledge that a document may exist is insufficient to establish a person has *actual notice of which materials therein are intended to be incorporated*.<sup>22</sup> The APA requires agencies to use precise and complete language clearly identifying material that is intended to be mandatory, especially when incorporating unpublished material into a final rule.<sup>23</sup> At best, maintenance providers have the ability to obtain knowledge that a manual or standard practice exists, but that does not establish actual notice of which requirements therein must be followed in order to comply with the parent AD. This renders any alleged requirements in an unpublished document unenforceable.

Even more problematic is the agency’s determination that maintenance providers need not follow the documents that are supposedly “reasonably available” in an AD.<sup>24</sup> The FAA’s IBR policy is a non sequitur: On one hand, unless made mandatory through notice and comment rulemaking, maintenance providers are free to disregard manufacturer maintenance information in favor of other acceptable methods, techniques or practices.<sup>25</sup> On the other hand, the FAA finds maintenance providers have actual notice of the mandatory

---

<sup>21</sup> *Id.*

<sup>22</sup> The authority the FAA cites for the proposition that maintenance providers have actual notice of the specific requirements in multi-tiered references is clearly distinguishable and inapplicable to the present situation. Reliance on [U.S. v. Bowers, 920 F.2d 220 \(4th Cir. 1990\)](#) is unavailing because the unpublished document at issue in that case (a tax form) did not impose substantive obligations requiring it to be published; the defendant was convicted under the statute criminalizing tax evasion. [Tearney v. NTSB, 868 F.2d 1451 \(5th Cir. 1989\)](#) is distinguishable because the FAA’s interpretation of a regulation was directly communicated to the certificate holder by his employer via internal memorandum. [U.S. v. Mowat, 582 F.2d 1194 \(9th Cir. 1978\)](#) is likewise distinguishable because direct and circumstantial evidence (signs and a media campaign) conclusively established that defendants knew that entry upon a naval proving ground was criminal trespass. Furthermore, ARSA notes that the FAA’s reliance on a settled enforcement case with no precedential value fails to support the agency’s position.

<sup>23</sup> [1 C.F.R. § 51.9.](#)

<sup>24</sup> See, e.g., [Legal Interpretation to David M Schultz \(Mar. 25, 2009\)](#) (citing Memorandum to AFS-300 (Dec. 5, 2008) and explaining why manufacturers’ instructions and revisions to them are not mandatory unless made so by the FAA through notice and comment rulemaking); [Memorandum from Asst. Chief Counsel for Regulations to Sacramento FSDO, Legal Interpretation of “Current” as it applies to Maintenance Manuals and Other Documents Referenced in 14 C.F.R. §§ 43.13\(a\) and 145.109\(d\), \(Aug. 13, 2010\)](#) (discussing *inter alia* [§ 145.109\(d\)](#)’s requirement for repair stations to possess certain documents but that section does not determine which version of the documents must be followed when completing the work).

<sup>25</sup> See, e.g., [14 C.F.R. § 43.13\(a\)](#) (stating maintenance providers must use the methods, techniques, and practices contained in manufacturer maintenance manuals, or Instructions for Continued Airworthiness, or *other methods, techniques, and practices acceptable to the Administrator*); [Legal Interpretation to Michael D. Busch \(Aug. 11, 2006\)](#) (stating that [§ 43.13\(a\)](#) “provides a number of options when performing work,” including manufacturer maintenance manuals, but cautioning that SBs referenced therein are not mandatory; at most the data, methods, techniques and practices referenced in the SB are acceptable to the Administrator).

RE: Reconsideration of Legal Interpretation dated January 27, 2014.

manufacturer maintenance information simply because it may be reasonably available. Somehow maintenance providers are supposed to divine when maintenance information is mandatory and when it is not. The FAA's failure to comply with the APA has led to considerable confusion within the industry and threatens to jeopardize aviation safety.

### **Conclusion and Requested Relief.**

Aviation safety demands that the FAA clearly articulate the requirements for complying with an AD if unsafe conditions are truly to be prevented and resolved. Both the agency and industry spend considerable time and expense navigating uncertain regulatory requirements. The FAA is in the best position to review the documents necessary to successfully address or resolve an identified unsafe condition. The time spent reviewing those documents, specifically identifying and seeking approval for their incorporation in the parent AD would be negligible compared to the time spent developing guidance to determine whether a person has actual notice, responding to requests for legal interpretations, and litigating enforcement cases.

For the foregoing reasons ARSA requests the FAA reconsider the legal interpretation issued on January 27, 2014 and revise Orders 8110.117A and 8110.103A accordingly.

Sincerely,



Ryan M. Poteet, Esq.  
Regulatory Affairs Manager

*Enclosures: ARSA Request for Legal Interpretation Re FAA Order 8110.103A, App. A  
(Aug. 28, 2013)  
Legal Interpretation to ARSA (Jan. 27, 2014)*

cc: Douglas R. Anderson	douglas.anderson@faa.gov
Kim Young	kim.young@faa.gov
Marshall S. Filler	marshall.filler@arsa.org
Sarah MacLeod	sarah.macleod@arsa.org



121 North Henry Street  
Alexandria, VA 22314-2903  
T: 703 739 9543 F: 703 739 9488  
arsa@arsa.org www.arsa.org

August 28, 2013

Delivered by facsimile: 202 267 3227  
Delivered by email; read receipt requested: Mark.bury@faa.gov  
Original delivered by Certified Mail  
Return Receipt Requested  
Receipt No: 7012 2920 0001 1065 7647

Mr. Mark Bury  
Deputy Assistant Chief Counsel, International  
Law, Legislation and Regulations Division  
Office of the Chief Counsel  
Federal Aviation Administration  
800 Independence Avenue SW  
Washington, DC 20591-0001

Re: Incorporation by Reference – Inaccuracy in 8110.103A Appendix A, A-1 to A-2

Dear Mark:

The Aeronautical Repair Station Association (ARSA) requests a legal interpretation confirming that:

(1) The language in Order 8110.103A question "f," as stated below, is incorrect.

*Question: The AD requires that I accomplish specific instructions in a SB. Those instructions require actions from a manual, and the manual requires actions from a standard practice manual. My operating procedure differs from the standard practice manual. Do I need an AMOC to keep using my operating procedure?*

*Answer: Yes. You must accomplish the specific instructions in the SB specified in the AD, including any second- or third-tier documents that are required to complete the action(s).*

(2) The question and answer will either be corrected or removed from the document forthwith.

### **Regulatory Background**

The Administrative Procedure Act (APA)<sup>1</sup> requires that an agency obtain the approval of the Director of the Federal Register for each document it wishes to incorporate by

---

<sup>1</sup> 5 U.S.C. § 552(a)(1).

Re: Incorporation by Reference – Inaccuracy in 8110.103A Appendix A, A-1 to A-2

reference (IBR) in a final rule. An airworthiness directive (AD) is part of the Code of Federal Regulations, and is therefore subject to the APA requirements concerning IBR.<sup>2</sup>

The regulations governing IBR are clear;<sup>3</sup> the cited language in Order 8110.103A does not comply with these requirements for the following reasons.

(1) Title 14 Code of Federal Regulations (CFR) § 39.27 makes it clear that a service bulletin (SB) referenced by the AD becomes a part of the AD. The FAA must obtain approval for each and every document that is IBR'd in the AD, not just the SB. The FAA acknowledges this fact in Order 8110.117, which states, "Remember that a reference to another document in an SB that is IBR'd in an AD does not constitute IBR'ing of the other document. The FAA must obtain approval from the OFR for each document that is IBR'd in an AD."

(2) To be eligible for approval for IBR, Title 1 CFR § 51.7 requires that the material is "published data, criteria, standards, specifications, techniques, illustrations, or similar material," reduces the volume of material published in the Federal Register, and is "reasonably available to and usable by the class of persons affected by the publication."

The "second- and third-tier documents" must conform to these requirements. Merely referring to an SB does not incorporate the documents mentioned in the SB, unless and until each document meets the criteria stated in 1 C.F.R. § 51.7.

(3) Title 1 CFR § 51.9 requires that the IBR is "as precise and complete as possible and shall make it clear that the incorporation by reference is intended and completed by the final rule document in which it appears."

To qualify, the IBR must use the words "incorporated by reference"; state the title, date, edition, author, publisher, and identification number of the publication; inform the user that the publication is a requirement; and make an official showing that the publication is available "by stating where and how copies may be examined and readily obtained."

## Conclusion

The Order 8110.103A answer to question "f," neither makes clear what exactly is "required to complete the action(s)," nor complies with the regulations set forth in Title 1 CFR. part 51.

---

<sup>2</sup> See, 14 C.F.R. § 39.13.

<sup>3</sup> See, 1 C.F.R. part 51.

Mr. Mark Bury  
August 28, 2013  
Page 3 of 3

Re: Incorporation by Reference – Inaccuracy in 8110.103A Appendix A, A-1 to A-2

Congress spoke directly on this issue in section 552(a)(1) of the APA, which states “a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register* and not so published.”

The regulations in part 51 set out clear requirements for material to be IBR'd, which are not contemplated by either the question or the answer to “f.” Thus, allowing the language to remain is inaccurate and misleading to those affected.

ARSA therefore requests an interpretation confirming the language in Order 8110.103A question “f” is incorrect, and that it is immediately changed or removed.

Your Servant,

A handwritten signature in blue ink, appearing to read "Sarah MacLeod". The signature is fluid and cursive, with the first name "Sarah" and last name "MacLeod" clearly distinguishable.

Sarah MacLeod  
Executive Director

Regulations/Legislation cited:

5 U.S.C. § 552(a)(1)  
1 C.F.R. § 51.7  
1 C.F.R. § 51.9  
14 C.F.R. § 39.13  
14 C.F.R. § 39.27



U.S. Department  
of Transportation  
**Federal Aviation  
Administration**

Office of the Chief Counsel

800 Independence Ave., S.W.  
Washington, D.C. 20591

JAN 27 2014

Sarah MacLeod  
Executive Director  
Aeronautical Repair Station Association  
121 North Henry Street  
Alexandria, VA 22314-2903

Dear Ms. MacLeod:

This responds to your request for a legal interpretation confirming that certain language in FAA Order 8110.103A is incorrect. Specifically, the order states:

**f. Question:** The AD [airworthiness directive] requires that I accomplish specific instructions in a SB. Those instructions require actions from a manual, and the manual requires actions from a standard practice manual. My operating procedure differs from the standard practice manual. Do I need an AMOC to keep using my operating procedure?

**Answer:** Yes. You must accomplish the specific instructions in the SB specified in the AD, including any second- or third-tier documents that are required to complete the action(s).

In your letter, you state that second and third-tier documents are not approved for incorporation by reference (IBR) in accordance with regulations of the Administrative Committee of Federal Register (1 CFR part 51). You also quote the following language from 5 U.S.C. 552(a)(1): “a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register* and not so published.” From this you conclude that the quoted language from Order 8110.103A is incorrect.

The quoted language from Order 8110.3A is correct. Your quotation from § 552(a)(1) is incomplete. For purposes of analyzing your request, the language you omitted is essential: **“Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published.”** (Emphasis added) This exception recognizes the long-standing legal principle that actual notice is at least as effective as constructive notice. For many years, courts have recognized that persons are subject to requirements of which they have actual notice, even if the issuing agency has not published them in the Federal Register or obtained approval for IBR.<sup>1</sup>

<sup>1</sup> See, e.g., Teamey v. NTSB, 868 F.2d 1451 (1989) (Pilot on notice that taxiing with passengers standing is violation); U.S. v. Bowers, 920 F.2d 220 (1990) (Income tax evasion); U.S. v. Mowat, 582 F.2d 1194 (1978) (Criminal trespass)

The documents that are typically referenced as second or third-tier references in ADs are documents that most operators and maintenance providers use to perform maintenance on affected aircraft. These documents include aircraft maintenance manuals, overhaul manuals, standard practices manuals, and service bulletins. Under 14 CFR 145.109(d),<sup>2</sup> certificated repair stations are generally required to have these documents for aircraft on which they perform work. Therefore, if a repair station complies with this requirement, it would have actual notice of these referenced documents.<sup>3</sup>

As you may be aware, the FAA recently took civil penalty enforcement action against Aviation Technical Services, Inc. (ATS, an ARSA member) for failing to comply with an AD because it failed to accomplish instructions specified in a secondary reference in the AD. The administrative law judge upheld the FAA's finding of violation against ATS for failing to use those references, and the judge specifically found ATS had actual notice of those documents.<sup>4</sup> In his decision, the judge correctly recognized the effect of the actual notice exception to the requirement for publication. Whether a respondent has actual notice of secondary references in ADs would be a factual issue to be resolved in each case.<sup>5</sup>

Even if a person does not have actual notice of secondary references in ADs, that person would not be able to simply ignore the AD requirements. The AD itself is enforceable, and any primary reference (e.g., a service bulletin) that is properly approved for incorporation by reference is also enforceable. If the person does not have actual notice of a secondary reference and, therefore, is unable to use that reference to comply with the AD, or if, as stated in the quoted question, a person simply prefers to use a different method, 14 CFR 39.19 allows that person to seek approval for an alternative method of compliance (AMOC). Section 39.19 allows use of the AMOC only if it is approved by the identified ACO manager.<sup>6</sup> Under these circumstances, the

---

<sup>2</sup> "A certificated repair station must maintain, in a format acceptable to the FAA, the documents and data required for the performance of maintenance, preventive maintenance, or alterations under its repair station certificate and operations specifications in accordance with part 43. The following documents and data must be current and accessible when the relevant work is being done: (1) Airworthiness directives, (2) Instructions for continued airworthiness, (3) Maintenance manuals, (4) Overhaul manuals, (5) Standard practice manuals, (6) Service bulletins, and (7) Other applicable data acceptable to or approved by the FAA."

<sup>3</sup> Your letter references provisions of 14 CFR part 51. Since that part only contains requirements for obtaining IBR approval, they are not relevant to this response.

<sup>4</sup> Although ATS filed an appeal, before perfecting the appeal it settled the case for the full civil penalty amount awarded by the judge.

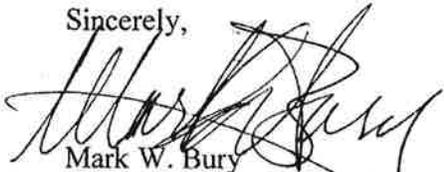
<sup>5</sup> We are requesting that the Aircraft Certification Service provide guidance to its Aviation Safety Engineers to determine that affected persons are likely to have actual notice of any secondary references before approving service bulletins and other documents that are intended to be referenced in ADs.

<sup>6</sup> **§39.19 May I address the unsafe condition in a way other than that set out in the airworthiness directive?** Yes, anyone may propose to FAA an alternative method of compliance or a change in the compliance time, if the proposal provides an acceptable level of safety. Unless FAA authorizes otherwise, send your proposal to your principal inspector. Include the specific actions you are proposing to address the unsafe condition. The principal inspector may add comments and will send your request to the manager of the office identified in the airworthiness directive (manager). You may send a copy to the manager at the same time you send it to the principal inspector. If you do not have a principal inspector send your proposal directly to the manager. You may use the alternative you propose only if the manager approves it.

person is neither "required to resort to" nor "adversely affected by" the secondary reference. The person is simply required to obtain approval for the method actually used. If a person records having complied with the AD without having either complied using all referenced documents or obtained approval for an AMOC, he would be in violation of the AD.

This response was prepared by Douglas Anderson, Northwest Mountain Deputy Regional Counsel, and was coordinated with the International Law, Legislation, and Regulations Division of the Office of the Chief Counsel. Please contact us at (202) 267-3073 if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark W. Bury". The signature is stylized and somewhat cursive, with a large loop at the end.

Mark W. Bury  
Assistant Chief Counsel for International Law,  
Legislation and Regulations