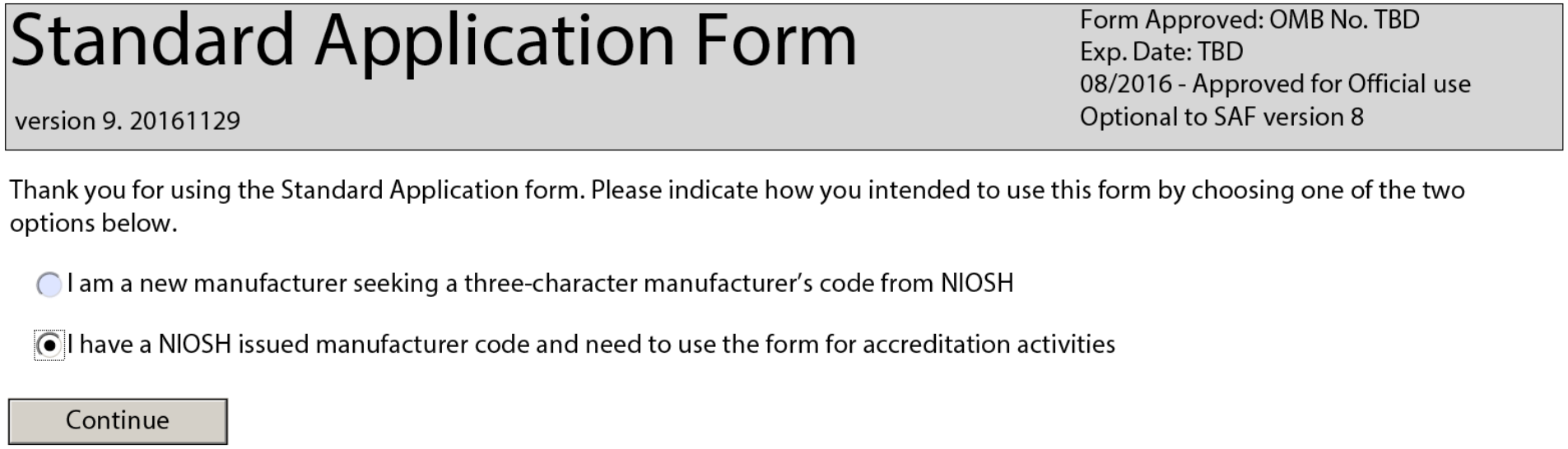
NIOSH Standard Application Form Module 2

Guidance on applying for a new air-purifying filtering facepiece respirator (FFR) approval

To be used in conjunction with the Standard Application Form (SAF) version 9

In this training module we will discuss how to fill out the NIOSH Standard Application Form (SAF v9) for a new respirator approval. The application demonstrated in this module will be specific to an air-purifying filtering facepiece respirator (FFR). To learn more about the application process for other classifications of respirators or types of applications, please reference the August 2015 standard application procedure for the approval of Respirators Under 42 CFR 84.



Standard Application Form

version 9. 20161129

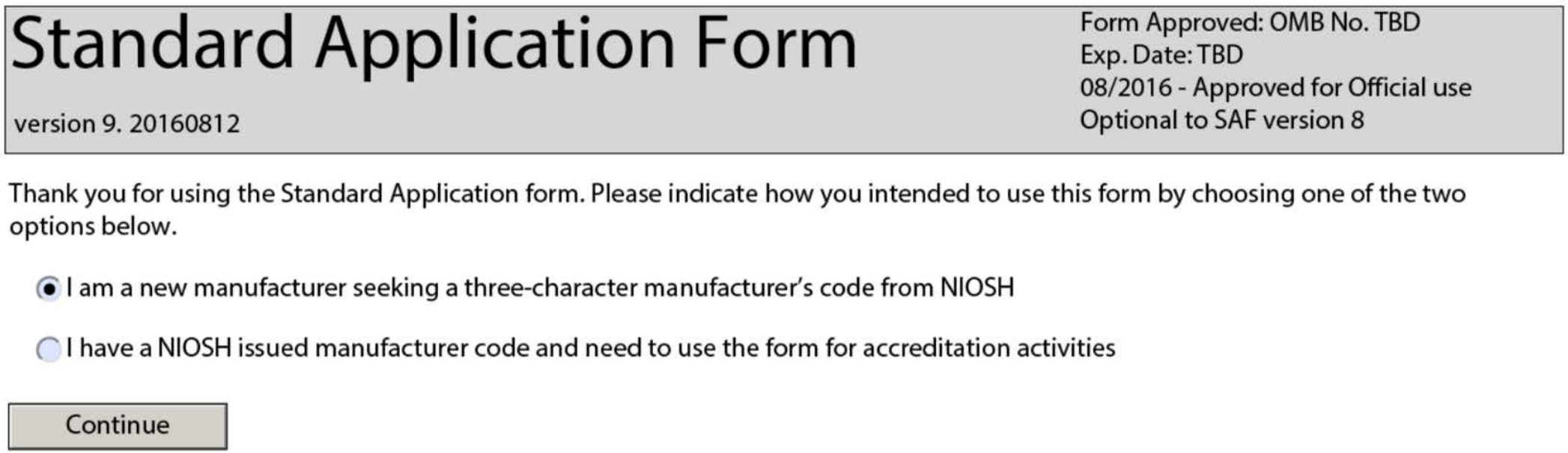
Form Approved: OMB No. TBD
Exp. Date: TBD
08/2016 - Approved for Official use
Optional to SAF version 8

Thank you for using the Standard Application form. Please indicate how you intended to use this form by choosing one of the two options below.

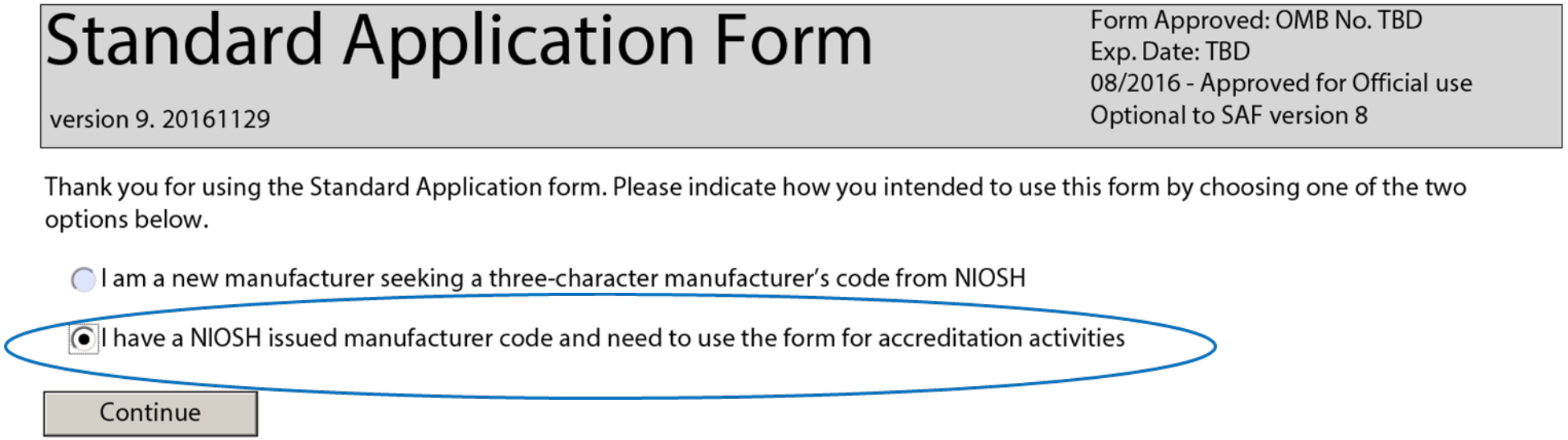
- ( ) I am a new manufacturer seeking a three-character manufacturer's code from NIOSH
- (•) I have a NIOSH issued manufacturer code and need to use the form for accreditation activities

Continue

Please Note: If this is your first attempt to gain a NIOSH respirator approval and you do not yet have a manufacturer code, please register as a new manufacturer by selecting the first option below and clicking the continue button to begin the application for a three-character manufacturer code. (Link to Training Module to Obtain a Manufacturer's Code)



If you already have a NIOSH-issued manufacturer code, select the second option to continue with the application for NIOSH approval. Clicking the continue button will display a warning that this action cannot be reversed. If you choose the wrong option, **do not save the form**. You cannot click back to this first question. Closing and re-opening the form without saving is the only way to make a different choice.



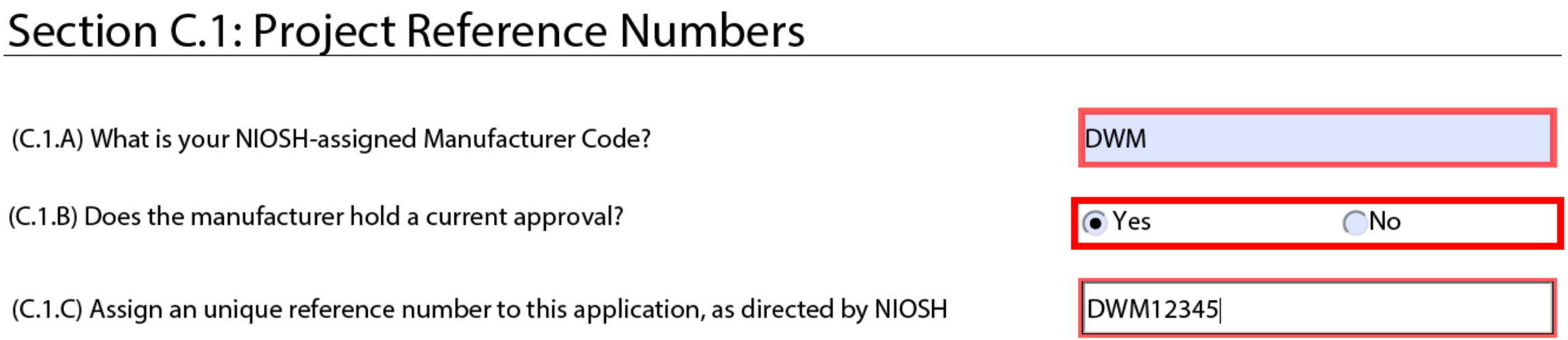
Boxes outlined in red indicate a required field.

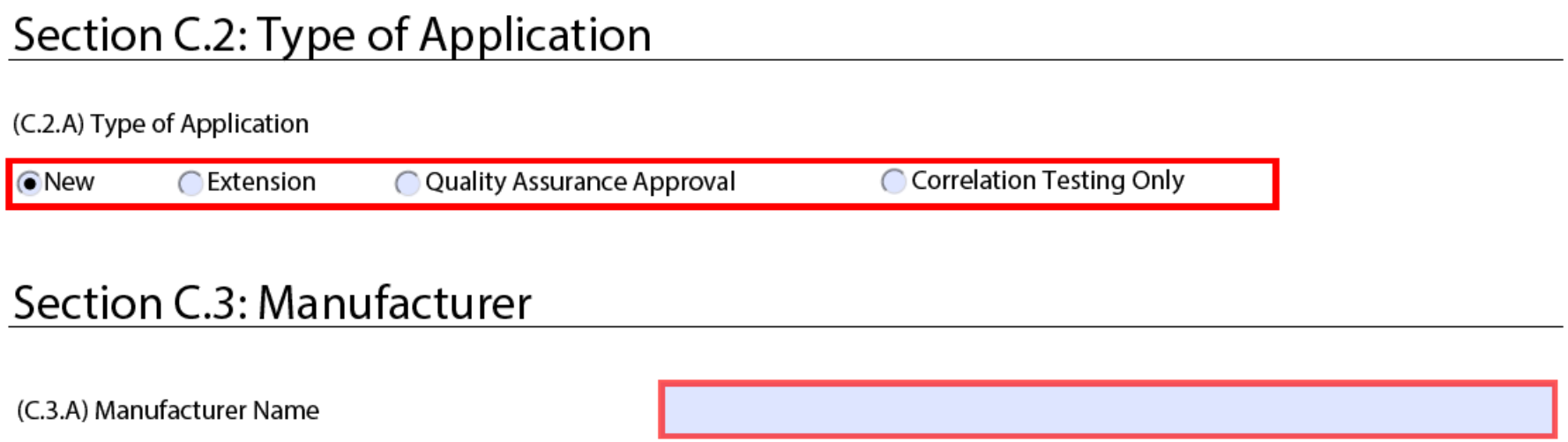
C.1.A Enter your NIOSH-assigned manufacturer code. For demonstration, we will use the mock code DWM.

C.1.B If you have other NIOSH respirator approvals in good standing, check “yes” to indicate that you are currently an approval holder. If you do not currently hold any approvals, select “no”.

C.1.C You must choose your own application reference number. This number should be unique to this application. Do not use a reference number that has ever been associated with another application or we will not be able to process this form. The only exception is on applications that are being amended at the request of NIOSH.

*The first three characters of this reference number must be your three-character manufacturer code.



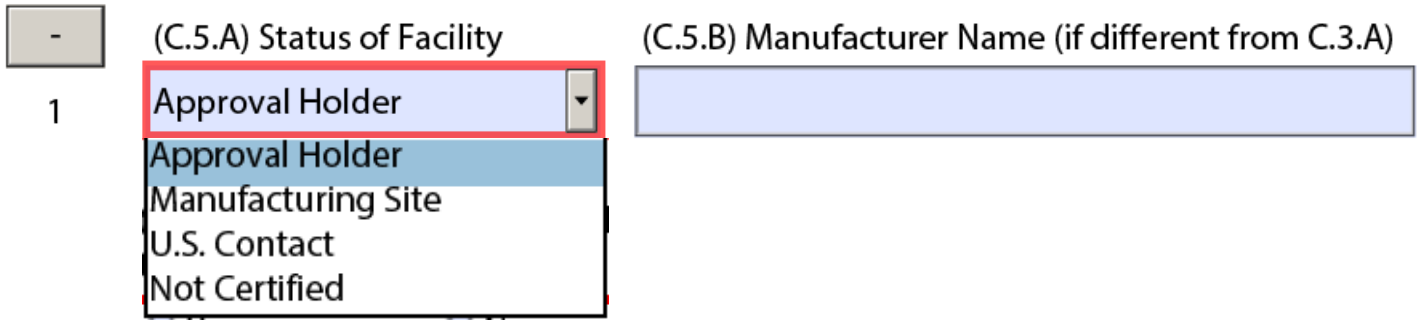


In Section C2 you will define the type of application

C.2.A In this module, we are applying for a **new** approval. Please refer to Section 1.2 of the 2016 APR-FFR Standard Application Procedure for definitions of the different types of applications.

C.3.A The manufacturer's name that you list in section C3 must match what's on file at NIOSH. If the company name or contact information has changed please contact the records room for further guidance .

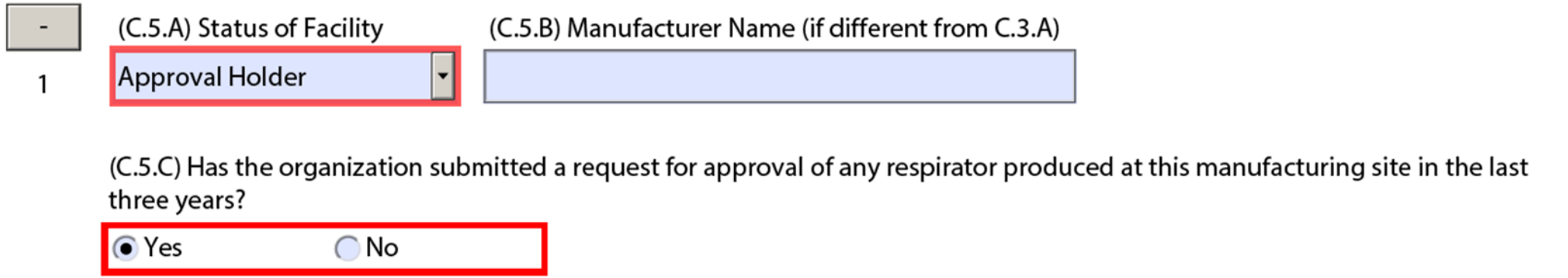
Section C.5: Application Representative



C.5.A The status of facility dropdown menu is in reference to the physical work location of the application representative. You will have the opportunity to add additional representatives/locations at the bottom of this section. You should identify any representatives who would be available to resolve any questions about this application.

Approval Holder – Choose this option if the representative works out of the office of the approval holder.
Manufacturing Site – Choose this option if the representative is a liaison from the respirator manufacturing site, which is not the same location as the approval holding company.
U.S. Contact – Choose this option if the company that is the approval holder is not located within the continental United States. This selection indicates that the person listed in this section is the domestic representative that will handle the application process correspondence.
Not Certified – Choose this option if you are filling out a new application and the representative is associated with a site that does not hold current approval.

Section C.5: Application Representative



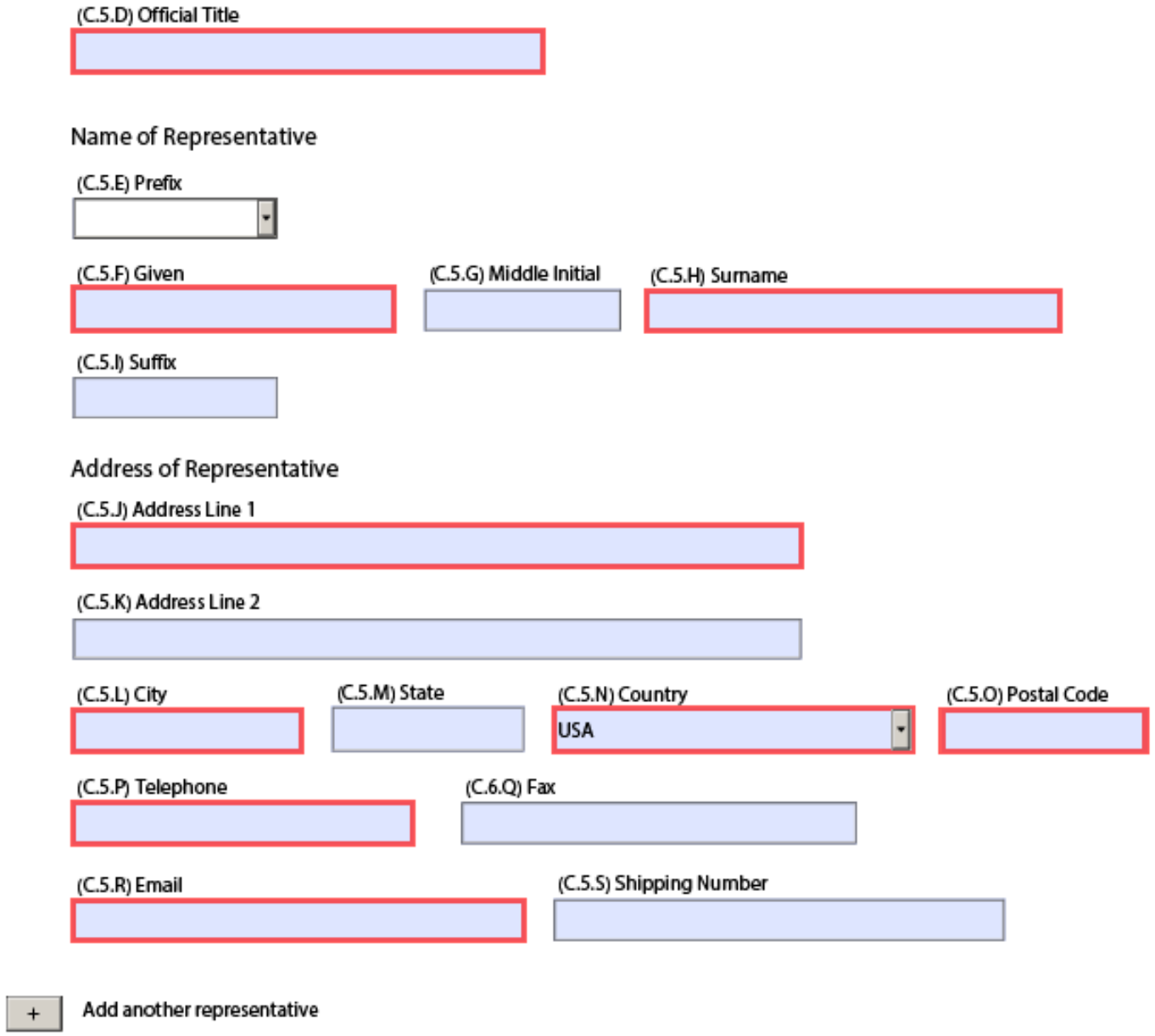
C.5.B: If the approval holder will manufacture the respirator associated with this application at an alternate location, please indicate that here by listing the manufacturing site name. Otherwise leave C.5.B empty.

C.5.C: If the manufacturing site has been used as the primary site for an approval or approval request in the last three years, indicate this by selecting “yes” to answer this question.

Note: *Any representatives listed on this application must already be on-file at NIOSH. If any of the contacts added here are not in NIOSH's system from previous applications, please contact the records room.*

C.5.D – C.5.R: List the name of the representative including his or her official working title, prefix such as Mr., Mrs., or Dr., first and last name, optional middle initial, and suffix such as Jr. or Sr. Proceed to enter the representative's work address and contact information.

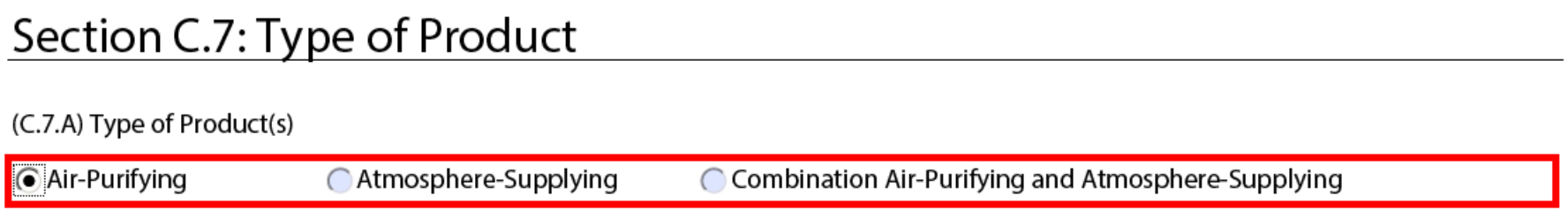
C.5.S: We will need your shipping account information if you want your samples returned. There may be limitations on shipping internationally. Please contact the records room to discuss international shipping options.



Section C.6: Date of Application

(C.6.A) Date of Application

C.6: Use the dropdown calendar to select the date of application. The date as listed here by the manufacturer **will not reflect the date of processing by NIOSH**.

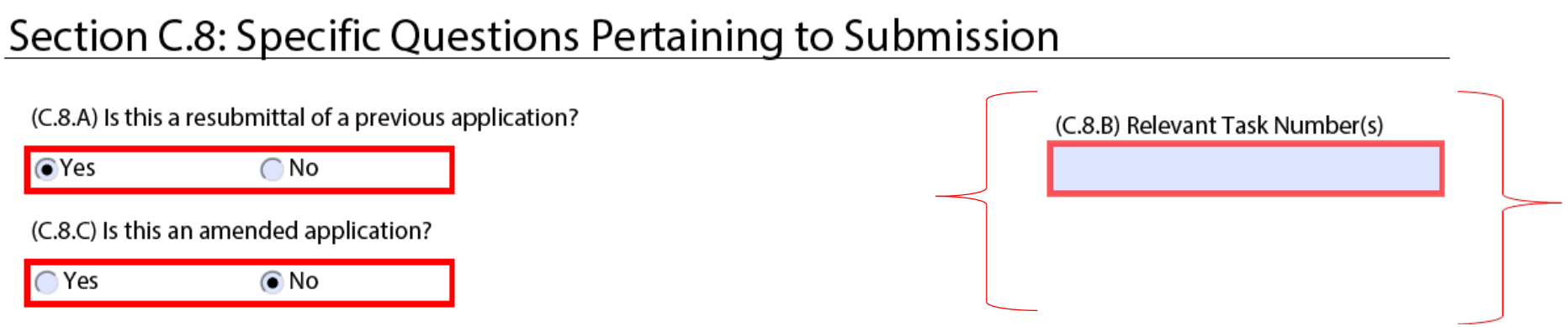


C.7.A:

Air-Purifying: A respirator that removes contaminants from the ambient air.

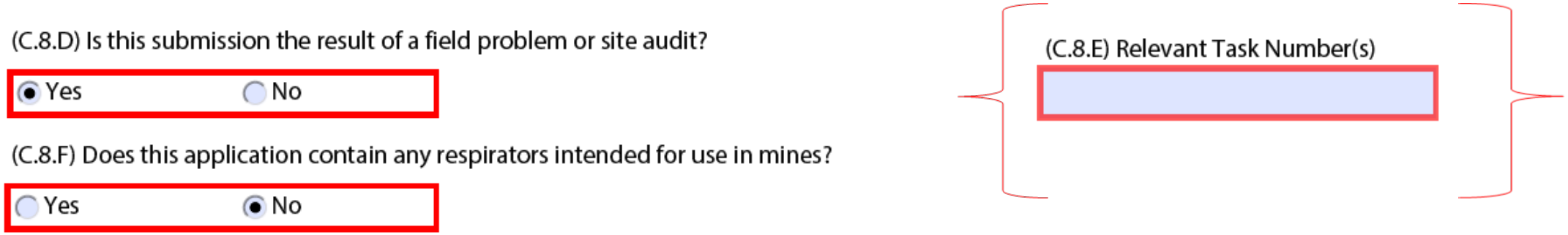
Atmosphere-Supplying: A respirator that provides air from a source other than the surrounding atmosphere.

As this application is for a filtering facepiece respirator, select “air-purifying”.



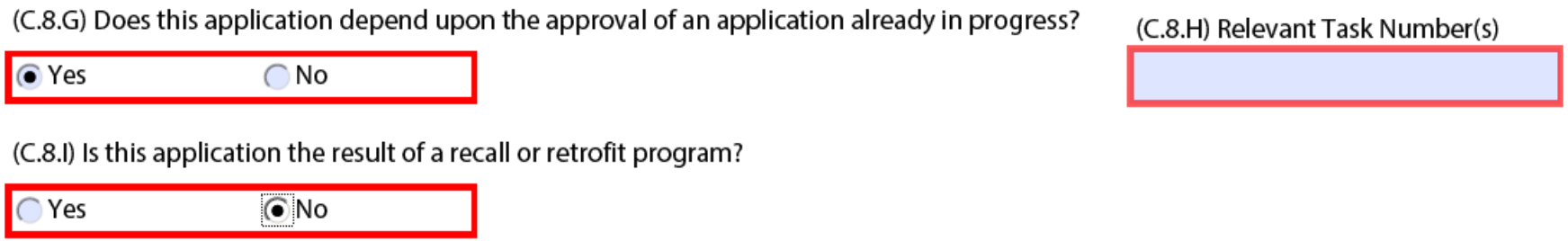
C.8.A: Is this application a resubmittal because it was previously denied? If "yes", **C.8.B** will populate, asking for all relevant task numbers concerning this re-submittal. (This does not apply to a withdrawn application.)

C.8.C: An amended application is submitted only at NIOSH's request in order to modify an open application that has an error. The application will retain the same Reference Number and Task Number.



C.8.D: If this application is in response to any kind of issue found during a site audit or certified product investigation (CPIP), **C.8.E** will populate so that you can enter the task number of the site/product audit or CPIP that led to this application. As this module is referring to new approvals, this answer will be “no”.

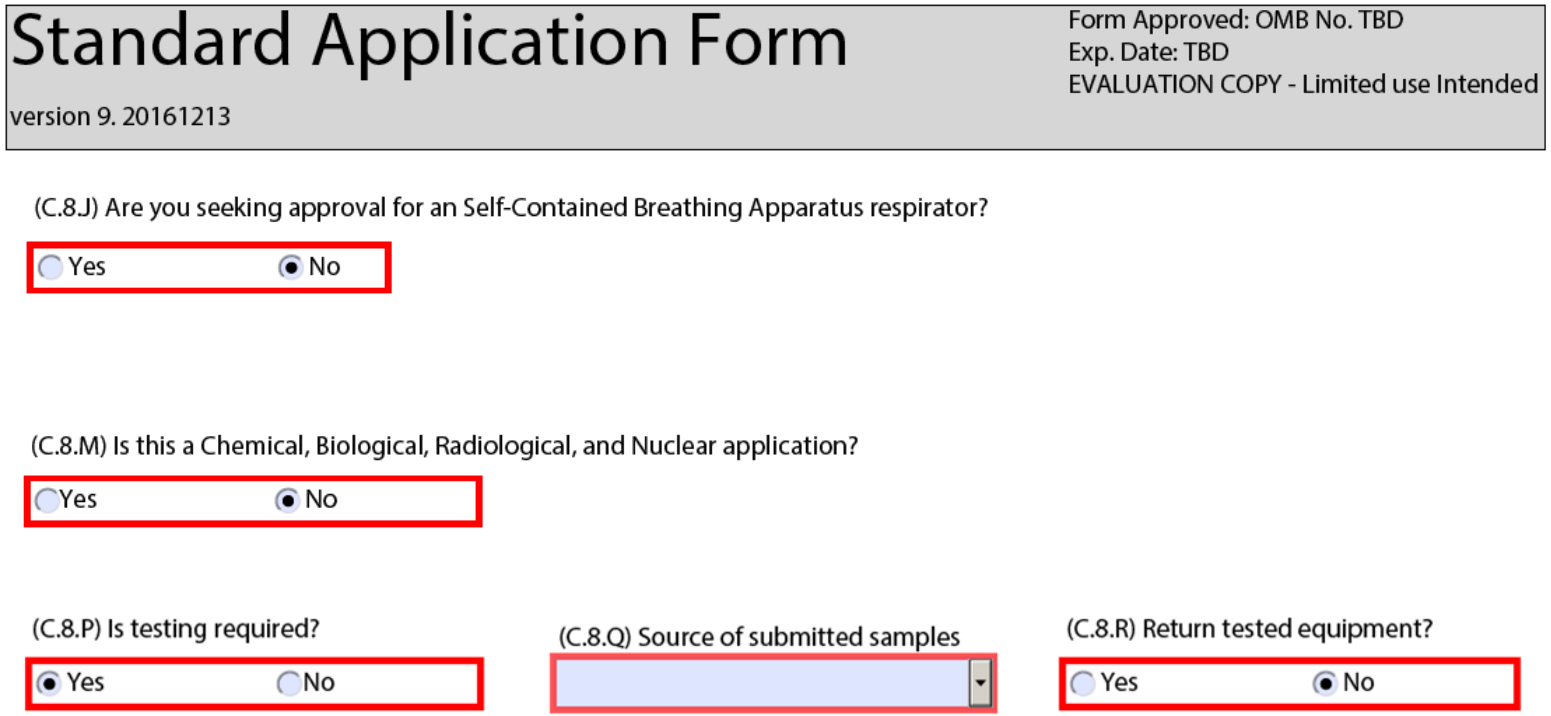
C.8.F: Since this is module is meant for filtering facepiece respirator applications, this answer will be “no”.



C.8.G example: A new filtering facepiece application is usually a stand-alone application, but based upon the documentation of the company, it can be linked to another project. Two common ways for a filtering facepiece application to become linked with another application is if the manufacturer uses one matrix to list multiple approvals or if the manufacturer places all of their Process Quality Plan (PQP) and inspection criteria within a shared document. If this application is linked with another, include the other's relevant task number in C.8.H.

If there are two or more applications that use the same assembly matrix, identify all subsequent applications in C.10, *Approval History*. The second and subsequent applications using the same assembly matrix cannot be processed until the first application is approved. If this section does not apply, check the "no" box.

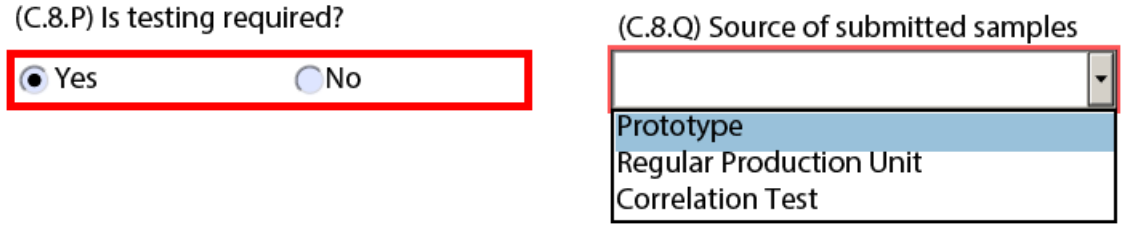
An FFR cannot be retrofit, therefore C.8.I will be checked "no".



C.8.J As you are applying for a filtering facepiece respirator approval, the answers to C.8.J through C.8.M will be "no".

However, since you are applying for a new respirator approval, the answer to C.8.P will be "yes". Question C.8.Q asks you to clarify the source of these samples. (See next slide for C.8.Q definitions)

Use C.8.R to indicate whether you require that NIOSH return test samples to the provided address after they have been tested.

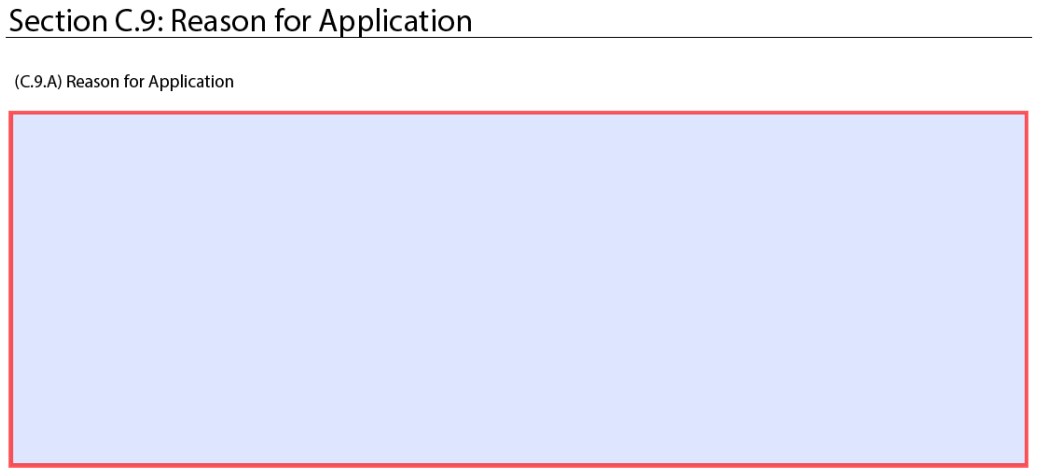


Prototype - Defined as a respirator or component that (a) involves a new design produced using rapid prototyping methods, temporary tooling, non-production tooling, or regular production tooling in a new fashion, and (b) has demonstrated by the applicant's pre-testing to meet 42 CFR 84 minimum design and performance requirements. Respirators may not be submitted for approval while in this defined prototype stage. NIOSH will request samples made on regular production tooling and production quality control (Ref. 84.30 (c)) if the approval holder request approval. For non-approval prototype testing use a new application form and state "Prototype Testing Only - Respirator is Not Submitted for Approval" in the "Reason for Application."

Regular Production Unit - A respirator or component made on regular production tooling, or that is identical to units made using regular production tooling, and is not made with any operations that will not be included in regular production. Tooling can be initial tooling or limited production tooling.

Correlation Test - Testing conducted to compare an applicant's test equipment and results to NIOSH's. The applicant must submit a new application with the wording "Correlation testing only; respirator is not submitted for approval" in the "Reason for Application" section.

Note: For more information about test samples, see the APR-FFR Standard Application Procedure, page 19.



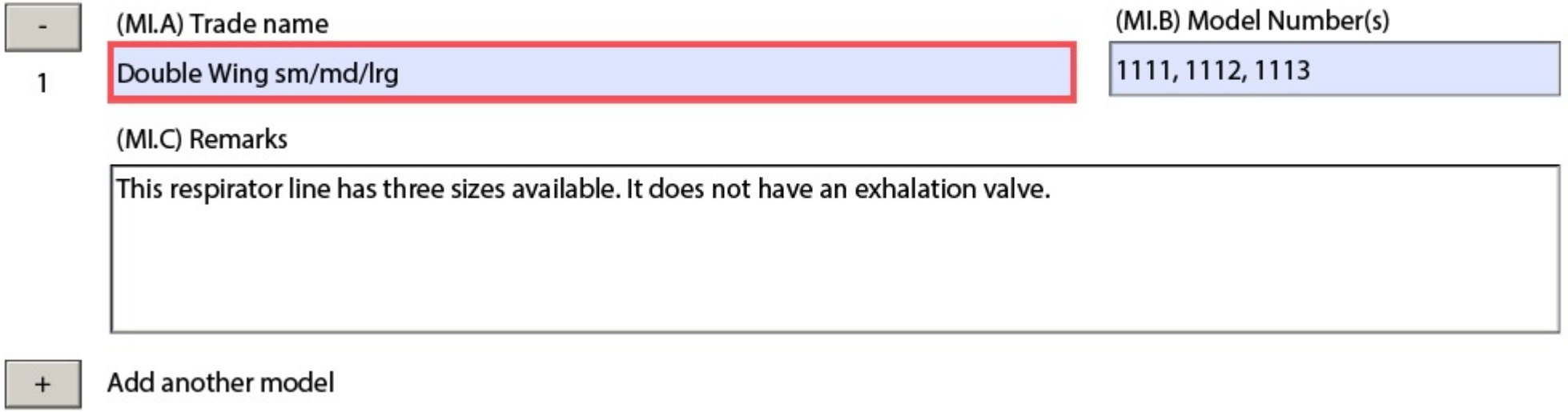
C.9 Reason for Application

Provide a complete, concise, descriptive reason for the application.
As part of the reason, be certain to address the following:

- Protection level of the respirator (e.g. N95, R95, P100)
- Identify if the respirator contains a carbon or nuisance layer
- Identify if the respirator has an exhalation valve
- Identify if the respirator has any unique features
- FDA clearance (e.g., surgical mask), if applicable
- If the respirator has an antimicrobial or other treatments applied to the respirator - FDA or EPA evaluation

Reference Section 9 (pages 15-16) of the September 16, 2016 Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators or Section C.9 (pages 27-28) of the August 2015 Standard Application Procedure for the Approval of Respirators Under 42 CFR Part 84.

Section MI: Model Information



MI.A is requesting the product trade name that uniquely identifies the respirator as sold on the public market. This name will be listed in the Certified Equipment List on the NIOSH website for public reference. You may have an umbrella name for a respirator family that has several models within it all under a single approval.

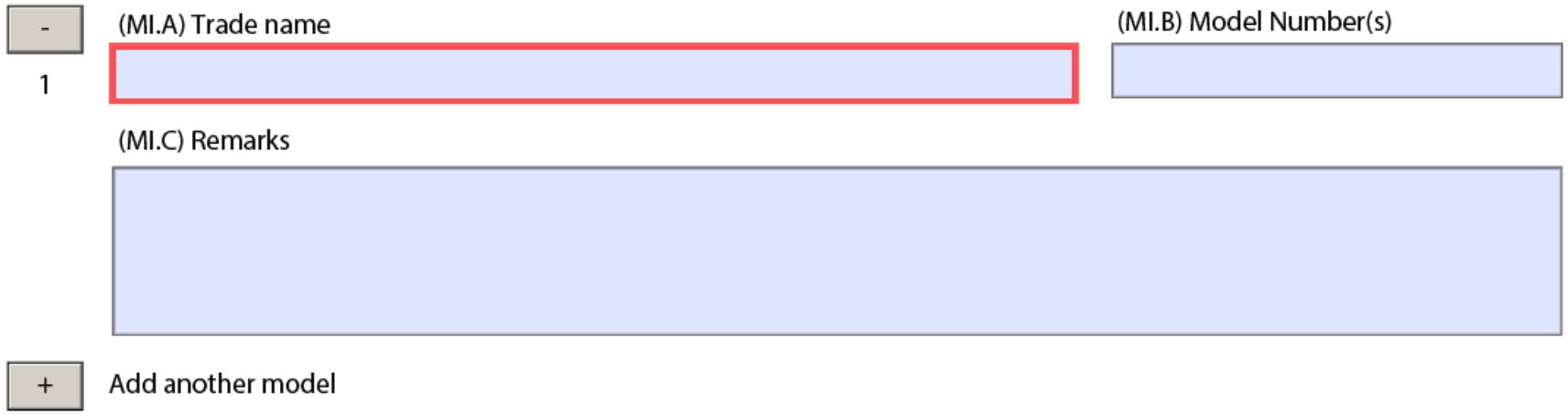
For an FFR approval, you will not have cause to click the + button to add another model.

Standard Application Form

version 9. 20161213

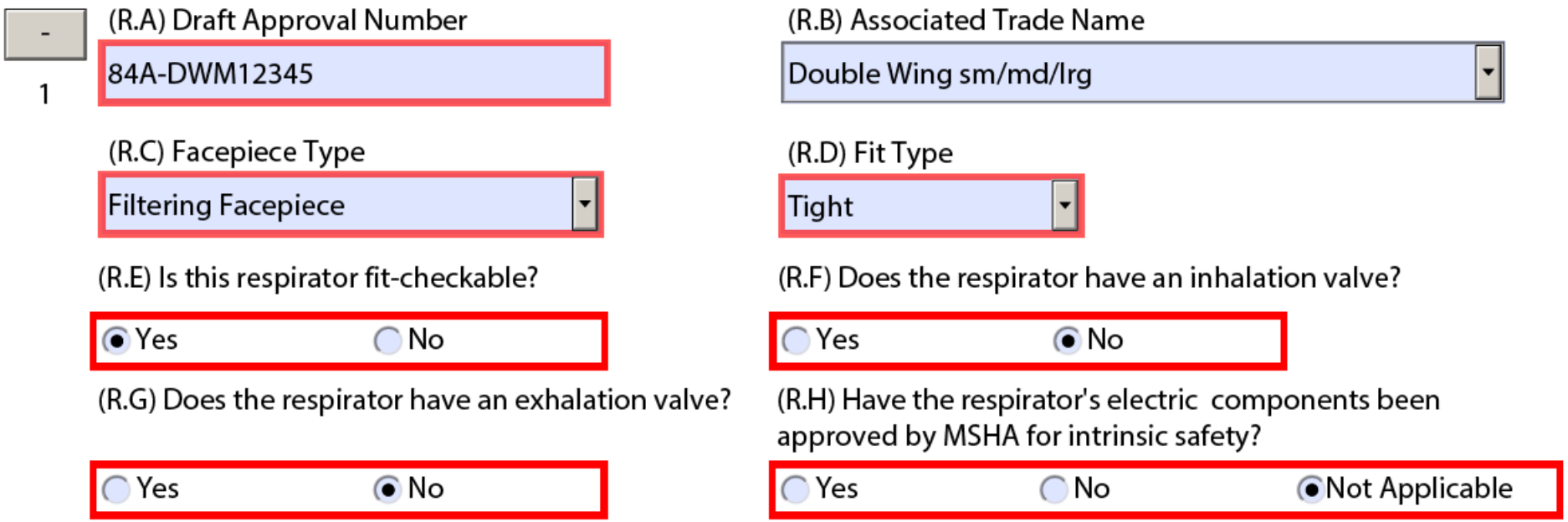
Form Approved: OMB No. TBD
Exp. Date: TBD
EVALUATION COPY - Limited use Intended

Section MI: Model Information



MI.B and **MI.C** are optional fields. Use MI.C to provide any necessary additional information about the model in this entry.

Section R: Specific Respirator Model Description(s)



R.A requires you to create a draft approval number. The character schedule for a filtering facepiece respirator is 84A. Combine this with your manufacturer's code and the reference number you picked to name your application. For our example, this application's approval number would be 84A-DWM12345. These draft approval numbers should appear on the assembly matrix and draft approval labels as well.

Section 7 Documents for Air-Purifying Filtering Facepiece Respirators

7.1 Example of Assembly Matrix for Air-Purifying Filtering Facepiece Respirators

(F) KEY:
X = Currently Approved in this Configuration

N = New Component or Configuration

"-" = Obsolete

R = Redesign

P = Pending

A = Accessory

Lucky Wing Manufacturing
1234 Manufacture Lane
Pittsburgh, Pennsylvania, USA
Phone: 412-555-1212

(G) TN or AAR# of Previously Approved or Pending Matrix: N/A

(H) Exploded-View Drawing Number: N/A; See Simplified Drawing of each facepiece

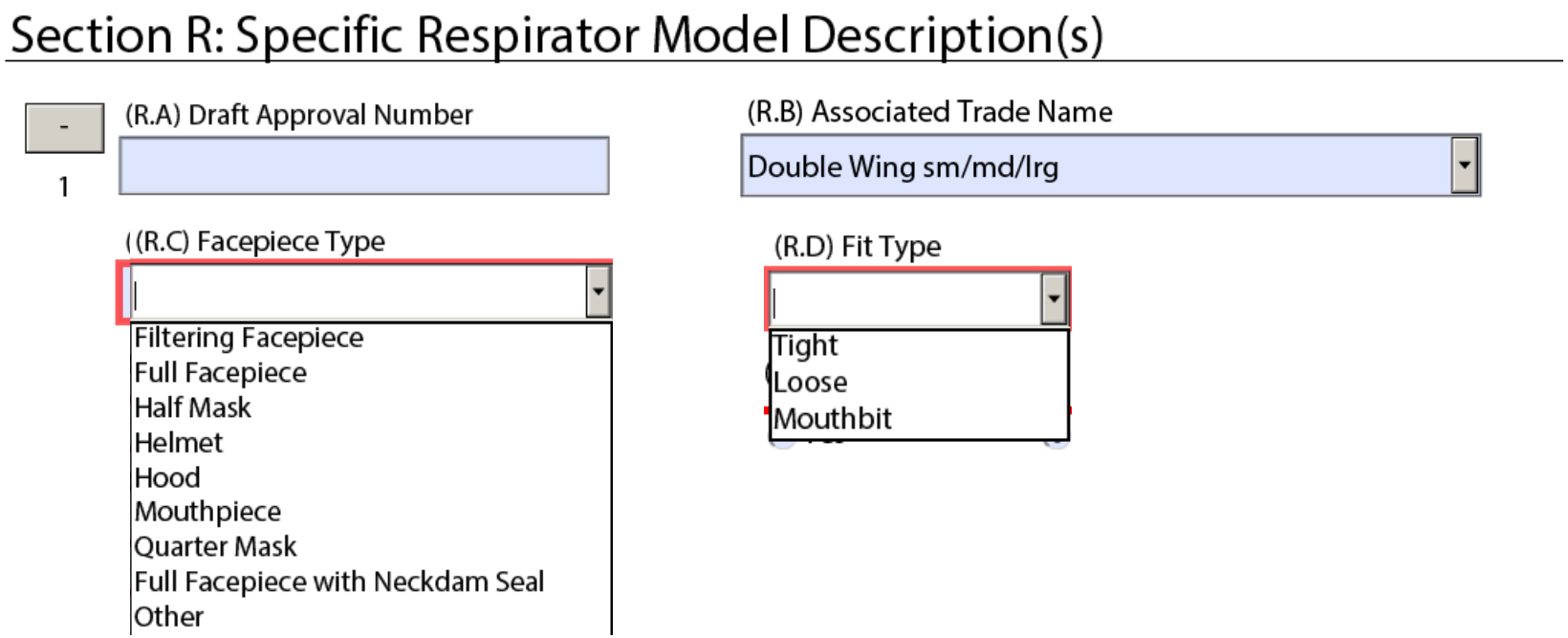
Date: August 1, 2015
Revision 1

Respirator L 10000 N95

(C)	(D)	(E)	(A) Respirator		
			Description	LW1000 N95	LW1000VN95V
			Revision	0	0
			Drawing Number	LWM001	LWM002
Applicant-Assigned Reference Number	NIOSH Approval Number, TC-	Protection	Model/Part Number	123456	123457
LWM101	84A-1234	N95		X	
LWM102	84A-1235	N95			R
NIOSH Task Number Where Component was Last Tested (If New, Indicate as "N")			(B)	TN-16000	TN-16001

The application's approval number should match what is listed on the assembly matrix.

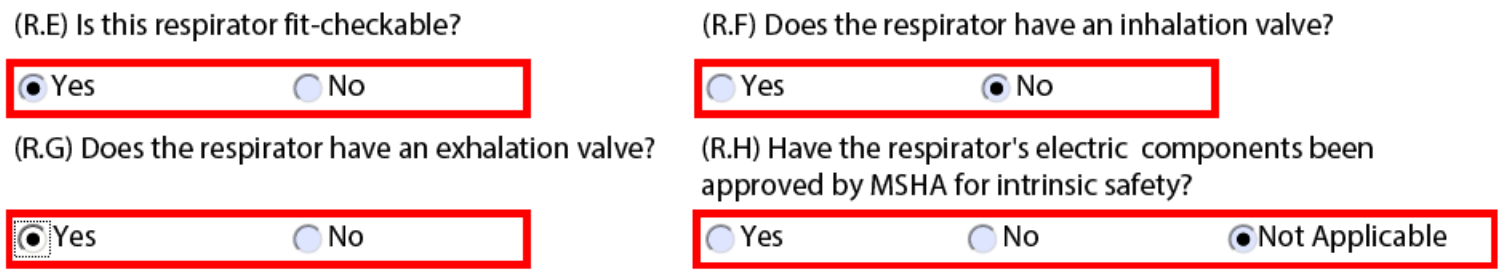
Example from the 2016 APR-FFR Standard Application Procedure, page 48.



R.B This drop down menu will be automatically populated with the trade names entered in the model section above. One of these identified trade names must be chosen to represent the model description in this section.

R.C Choose “Filtering Facepiece”

R.D Choose “Tight”

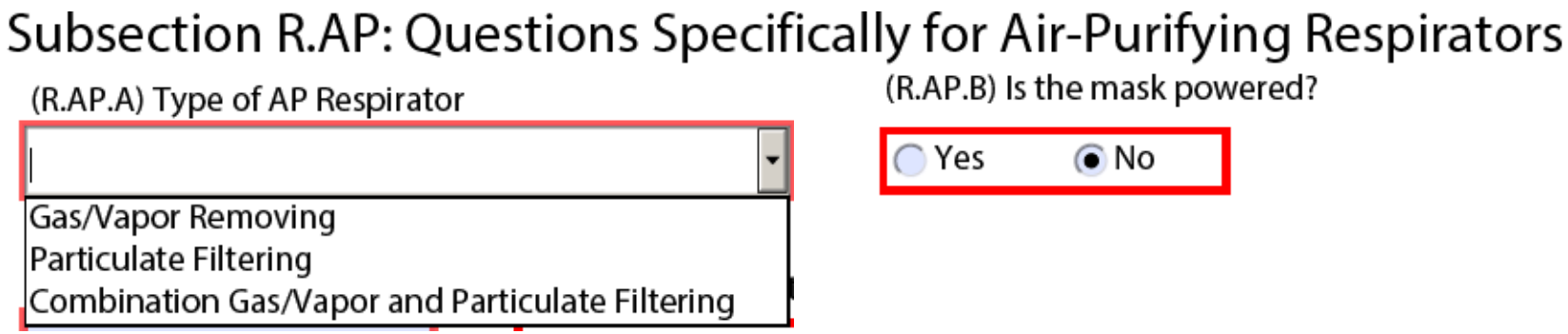


R.E. A filtering facepiece respirator should be fit checked, also known as a user seal check, therefore select “yes”.

R.F. FFRs do not have inhalation valves.

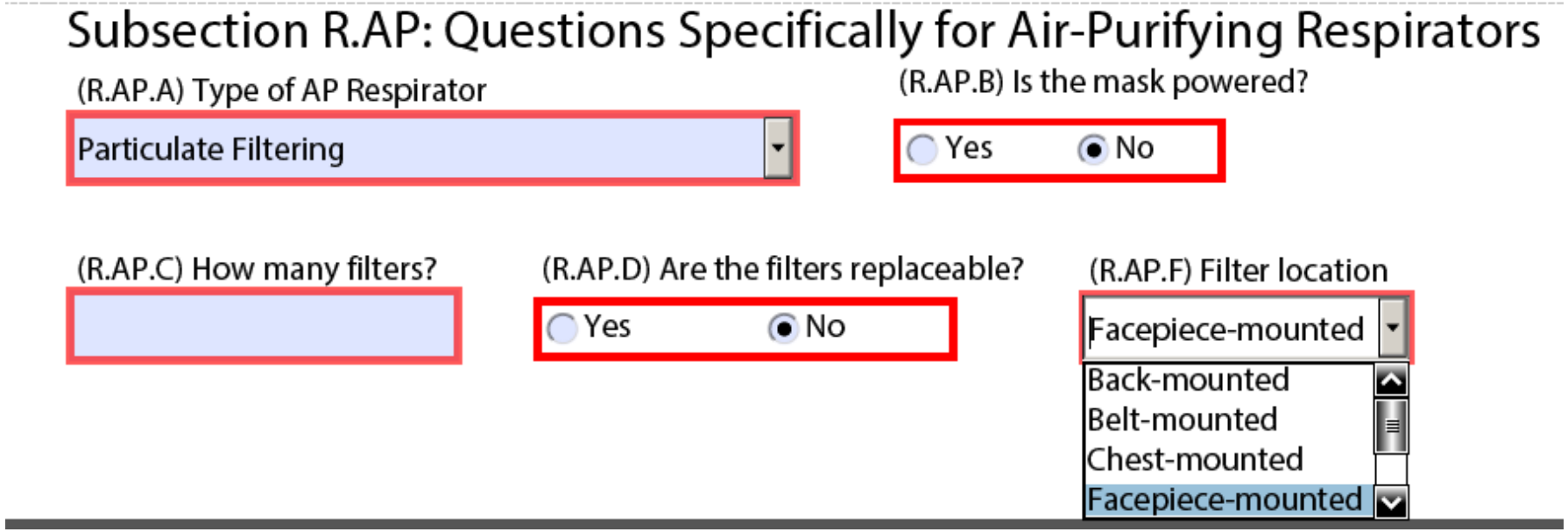
R.G. If the FFR model you are describing has an exhalation valve, indicate that in R.G.

R.H Because you are applying for an FFR approval, R.H. is not usually applicable.



R.AP.A: In this dropdown menu, select “Particulate Filtering”

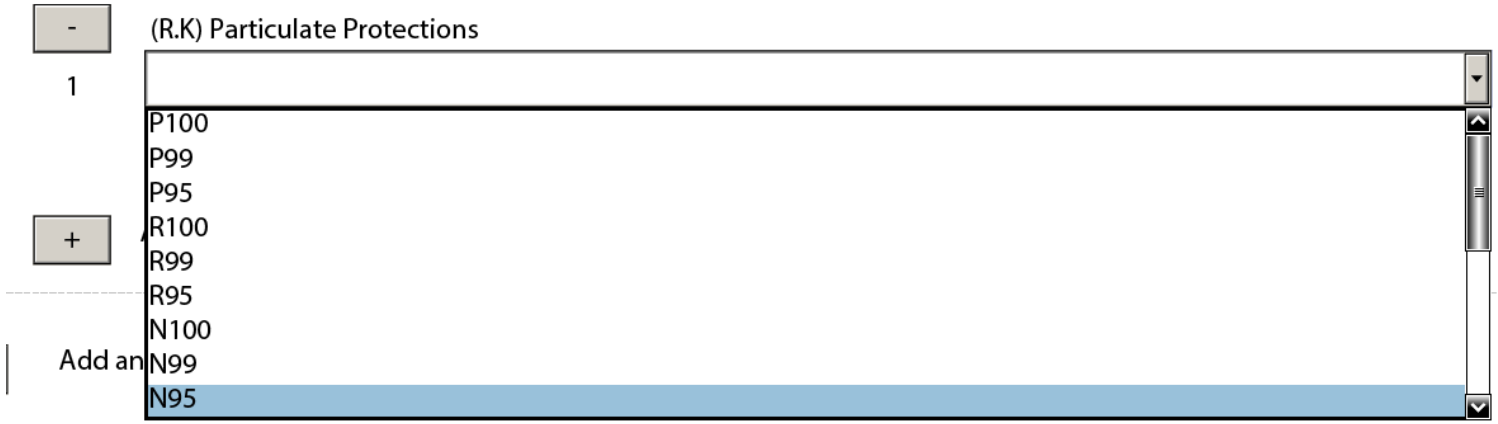
R.AP.B: Typically an FFR is not powered



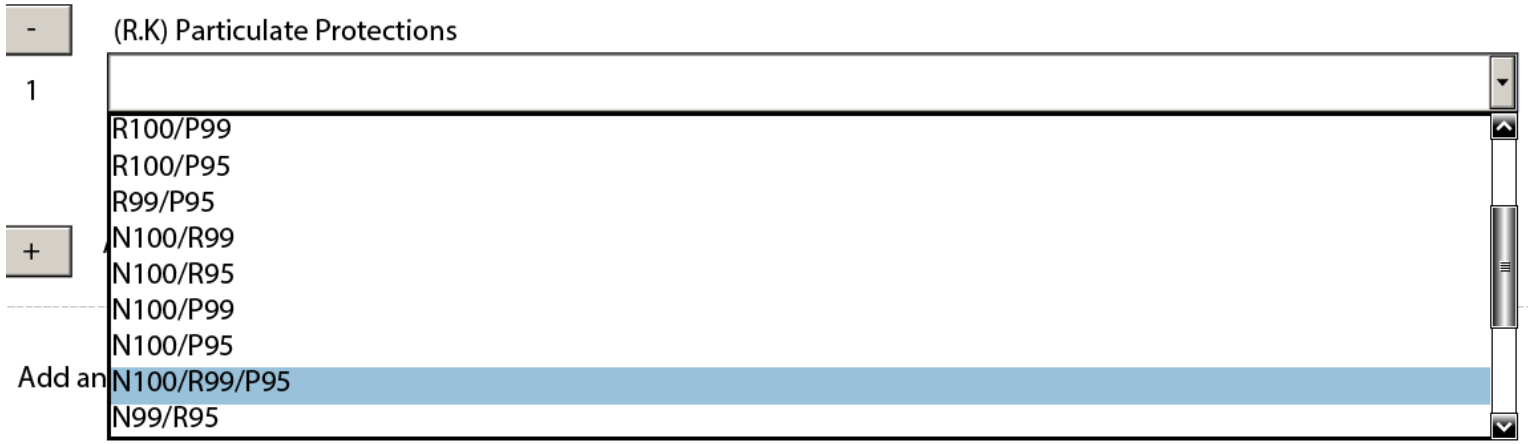
R.AP.C: An FFR will have one filter.

R.AP.D: FFR filters are not replaceable

R.AP.F: Select “Facepiece-mounted”



R.K: Select the FFR particulate protection level for this application.



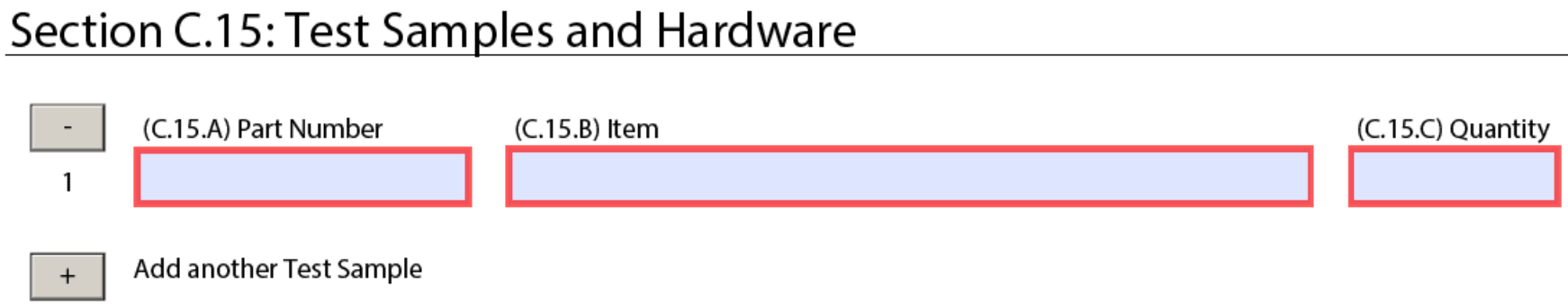
A list of acceptable multiple protections are listed on page 12 of the APR-FFR Standard Application Procedure. If a multiple level of protection is selected, NIOSH will require pretesting for all levels of protection and NIOSH will test at all levels of protection.

Section C.13: Pretest Data

Section C.13.A will be populated with all the applicable pretests for air-purifying respirators. You can select any pretests that the described respirator models have undergone.

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
5a	Filtering Facepieces - 42 CFR 84 Particulate Negative Pressure	3 4 7 51-56 57-59	Exhalation resistance Exhalation valve leakage (if present) Inhalation Resistance DOP for particulates NaCl for particulates	3 Exhalation valve assemblies (if present) 26 Filtering Facepieces for each type

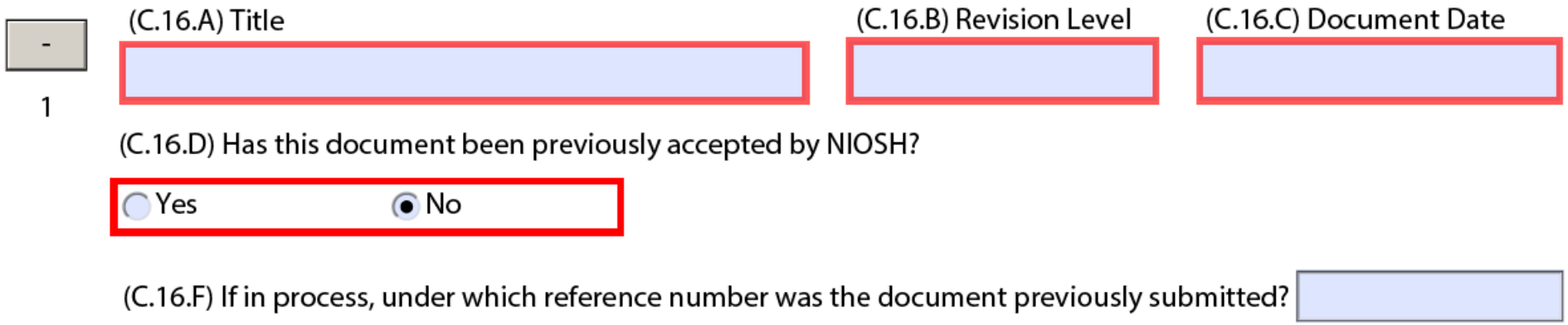
Above is the pretest data required for an FFR. For the required pretest data for all respirator types, see pages 17 and 18 in the 2016 FFR Standard Application Procedure. For more information about what each pretest entails, refer to the Standard Testing Procedures.



C.15.A Assign a part number to the test sample. This should be the part number identified on the product, assembly matrix, and label matrix, not the model number. This number must match any correlating entries in the assembly matrix as well as supporting documentation for pretests when applicable. If you are submitting items or samples for testing that are not on the assembly matrix, such as the exhalation valve, identify the part number of the items. Or, if no part number is available use the term “not available.”

C.15.B Use this field to enter the name and short description of the test sample. Use C.15.C to enter the quantity you are submitting for testing.

Section C.16: Quality Assurance Documents (Controlled Documents)

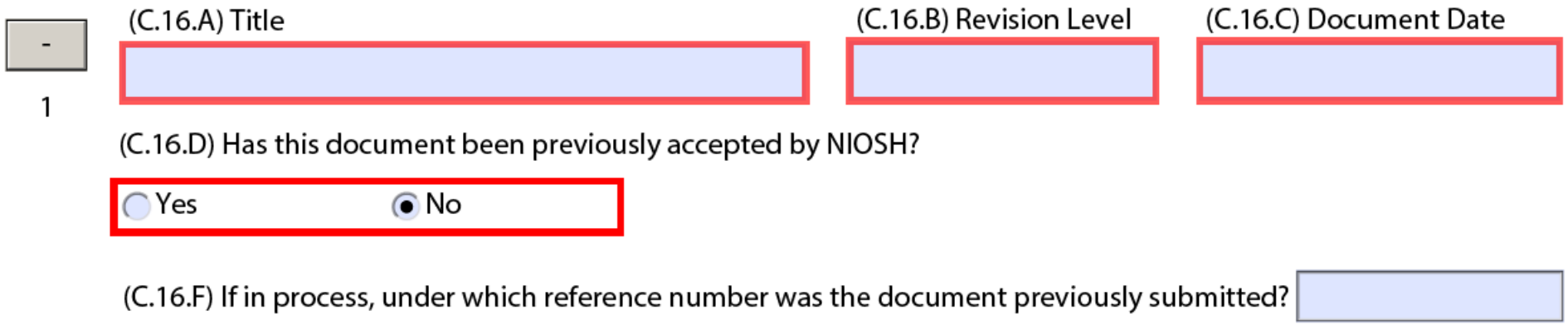


Enter the title of the respirators' quality assurance documents in C.16.A. We are looking for the document name, not the file name.

The only required quality assurance document to be listed in this section is the manufacturer's quality manual(s).

If the document has been approved in a previous project, the document should be listed in section C.16, but it should not be attached in section C.24. The previous task number information can be placed in the reason for application or history section.

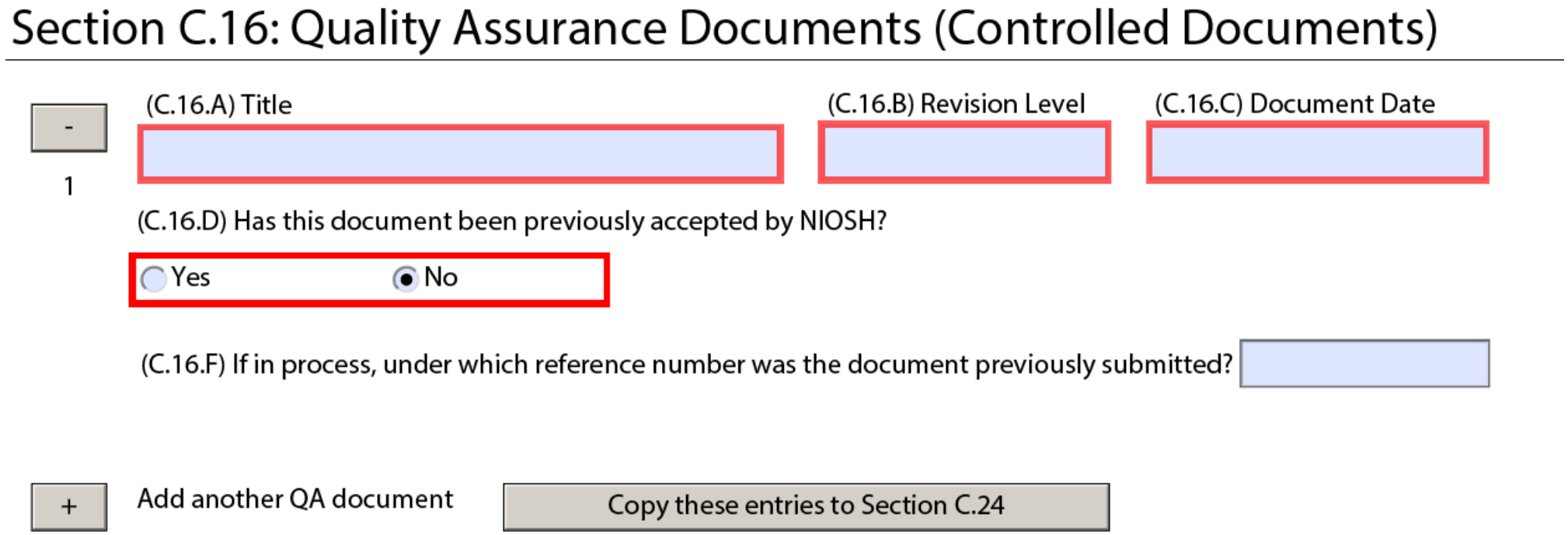
Section C.16: Quality Assurance Documents (Controlled Documents)



Other types of quality assurance documents, not required to be listed in section C.16 at this time, include:

- Related Product Quality Plan (PQP) flowcharts
- Sampling plan and classification of defect documents
- Related inspection documents
- Drawings
- Assembly Matrix

For more information, reference section 3, pages 20-21 of the FFR Standard Application Procedure

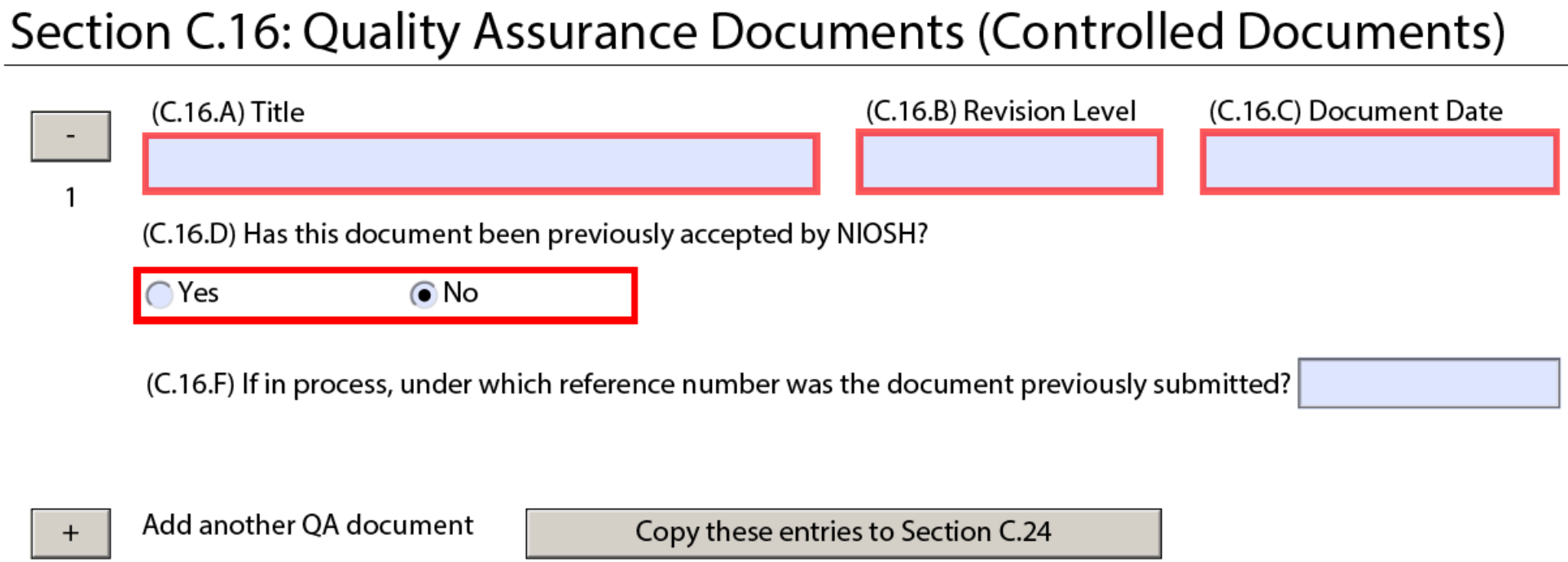


C.16.B: Indicate to what revision version/level the applicable quality assurance document refers.

C.16.D: This answer is “no” when you are a new company with your first approval or the addition of a new subcontracting facility.

The answer is “yes” when the quality manual is already approved.

C.16.F: This will not be applicable for a new FFR application. Leave this field blank.



A document specified in section C.16 may correlate to a document attached in section C.24. To minimize the duplication of effort, use the provided button to automatically add the entries to section C.24 with temporary file names and the title and revision level provided in the C.16 description.

Section C.17: Fees

Standard Application Fee: $200

Pay.Gov was used? (•) Yes ( ) No

(C.17.A) Transaction Amount

(C.17.B) Tracking Number

(C.17.C) Transaction Date

Section C.17: Fees

Standard Application Fee: $200

Pay.Gov was used? ( ) Yes (•) No

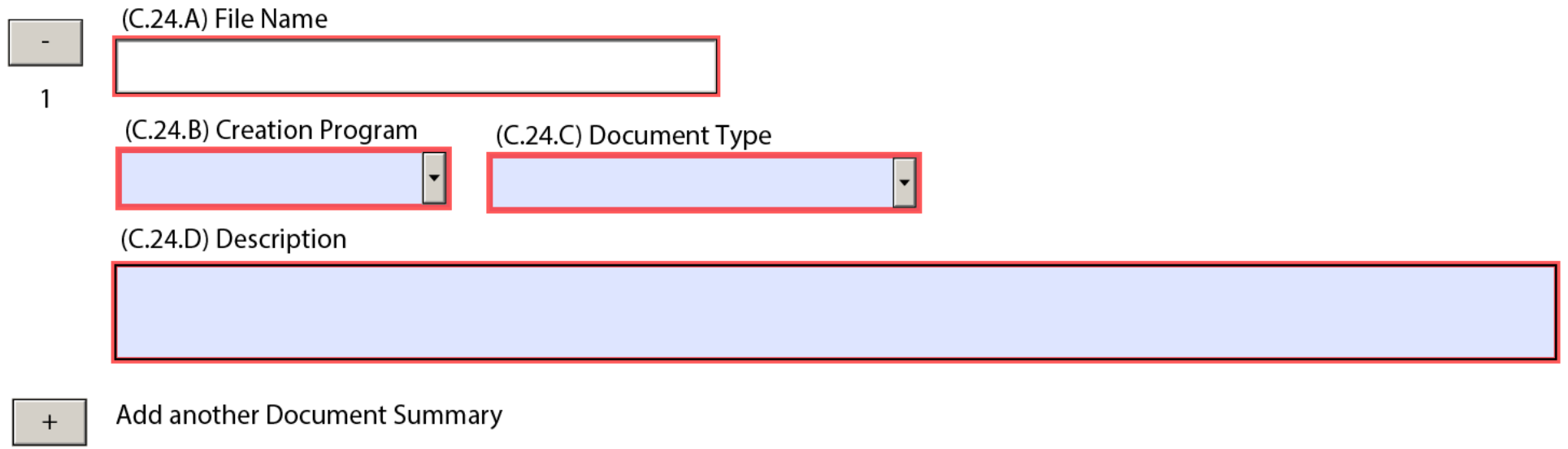
(C.17.A) Check Amount

(C.17.B) Check Number

(C.17.C) Check Issue Date

Section **C.17.A – C** will populate according to whether or not you used Pay.Gov to pay the standard application fee.

Section C.24: Summary of Related Documents



Any documents listed and attached in section C.24 must be checked in the Checklist that follows.

When submitting your application for an FFR, your checklist should include the items below. This is an example of what your checklist might look like, but please double-check your application to ensure that your checklist includes all the documents applicable to your application.

Each of these checked documents should be attached and included with your application package.

Checklist

- [x] Quality assurance manual *(If applicable)*
- [x] Product quality control plan
- [x] Assembly matrix
- [ ] CGA thread specifications
- [ ] Burst disc pressure range (SCBA only)
- [ ] DOT approval documentation
- [ ] Lens meets GGG-M-125d requirement
- [x] Exploded-view drawing
- [ ] Major components drawings *(Typically for an FFR, exploded view is the major component)*
- [x] Check *(If you did not use Pay.gov)*
- [x] User instructions
- [ ] Packaging art
- [ ] Special gas data
- [ ] End of service life indicator (EOSL or ESLI) data
- [x] List of related documents
- [ ] All test data sufficient to demonstrate compliance with 42 CFR part 84
- [x] TC numbers are entered into "(C.9.A) Reason for Application"

Draft Approval Labels

- [x] Approval label draft: Air-Purifying Respirator
- [ ] Approval label draft: Cartridge or Canister
- [ ] Approval label draft: Filter
- [ ] Approval label draft: Abbreviated Cartridge or Canister
- [x] Approval label draft: Abbreviated Filter
- [ ] Approval label draft: SCBA (in manual)
- [ ] Approval label draft: SCBA harness
- [ ] Approval label draft: SAR (in manual or on packaging)
- [ ] Approval label draft: Scrubber Label

I certify that the information contained in this application is correct and that if approved, no further changes will be made to the product(s) without prior written approval of the National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory and CVSD branch.

Initials of Authorized Representative:

When you have completed your application, authorize the document by electronically signing your initials. Save the document and email the application along with the other items “checked” in the list above to

recordsroom@cdc.gov