



OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT  
FACILITIES DEVELOPMENT DIVISION

APPLICATION FOR OSHPD PREAPPROVAL OF  
MANUFACTURER'S CERTIFICATION (OPM)

OFFICE USE ONLY

APPLICATION #: OPM-0460-13

OSHPD Preapproval of Manufacturer's Certification (OPM)

Type: ☒ New ☐ Renewal ☐ Update to Pre-CBC 2013 OPA Number: \_\_\_\_\_

Manufacturer Information

Manufacturer: Germfree Laboratories, Inc.

Manufacturer's Technical Representative: Ronald Lavicott

Mailing Address: 4 Sunshine Blvd. Ormond Beach, FL 32174

Telephone: 386-265-4343

Email: rlavicott@germfree.com

Product Information

Product Name: Compounding Aseptic Containment Isolator (CACI) & Compounding Aseptic Isolator (CAI)

Product Type: Compounding Aseptic Containment Isolator & Compounding Aseptic Isolator meeting USP and NIOSH guidelines.

Product Model Number: LFGI-3USP, LFGI-4USP, LFGI-6USP

General Description: LFGI functions as a Compounding Aseptic Containment Isolator (CACI) while operating under strong negative pressure to meet USP <800> and NIOSH recommendations. Additionally, functions as a Compounding Aseptic Isolator (CAI) under negative pressure to meet USP <797> regulations. Providing operator, a complete barrier from the materials being manipulated by working with a highly ergonomic glove system.

Applicant Information

Applicant Company Name: Sun Structural Engineering, Inc.


Contact Person: Changhua Sun

Mailing Address: 2091 Las Palmas Dr. Suite D Carlsbad, CA. 92011

Telephone: (760)438-1188

Email: sunengineering@sbcglobal.net

I hereby agree to reimburse the Office of Statewide Health Planning and Development review fees in accordance with the California Administrative Code, 2016.

Signature of Applicant: 

Date: 12-4-2017

Title: President

Company Name: Sun Structural Engineering, Inc.

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STATE OF CALIFORNIA – HEALTH AND HUMAN SERVICES AGENCY  
OSH-FD-700 (REV 12/16/15)

OSHPD

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**Registered Design Professional Preparing Engineering Recommendations**

Company Name: Sun Structural Engineering, Inc.  
Name: Changhua Sun California License Number: S4609  
Mailing Address: 2091 Las Palmas Dr. Suite D Carlsbad, CA. 92011  
Telephone: (760)438-1188 Email: sunengineering@sbcglobal.net

**OSHDP Special Seismic Certification Preapproval (OSP)**

- ☐ Special Seismic Certification is preapproved under OSP-  
(Separate application for OSP is required)  
☒ Special Seismic Certification is not preapproved

**Certification Method(s)**

- ☐ Testing in accordance with: ☐ ICC-ES AC156 ☐ FM 1950-16  
☐ Other\* (Please Specify): \_\_\_\_\_

\*Use of criteria other than those adopted by the California Building Standards Code, 2016 (CBSC 2016) for component supports and attachments are not permitted. For distribution system, interior partition wall, and suspended ceiling seismic bracings, test criteria other than those adopted in the CBSC 2016 may be used when approved by OSHDP prior to testing.

- ☐ Analysis  
☐ Experience Data  
☐ Combination of Testing, Analysis, and/or Experience Data (Please Specify): \_\_\_\_\_

**List of Attachments Supporting the Manufacturer's Certification**

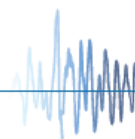
- ☐ Test Report ☒ Drawings ☒ Calculations ☐ Manufacturer's Catalog  
☐ Other(s) (Please Specify): \_\_\_\_\_

**OFFICE USE ONLY – OSHDP APPROVAL VALID FOR CBC 2016 & ALL PRE-2016 CODE BASED PROJECTS**

Signature: Jeffrey Kikumoto Date: 09-28-2018  
Print Name: Jeffrey Kikumoto  
Title: SSE  
Condition of Approval (if applicable): \_\_\_\_\_

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**OSHDP**

# OFFICE STATEWIDE HEALTH PLANNING AND DEVELOPMENT

## PRE-APPROVAL MANUFACTURER'S CERTIFICATION

### OPM - 0460 - 13

#### THIS PRE-APPROVAL CONFORMS TO THE 2016 CALIFORNIA BUILDING CODE

MANUFACTURER: GERMFREE LABORATORIES

EQUIPMENT TYPE: COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR  
AND COMPOUNDING ASEPTIC ISOLATOR  
LFGI-3USP, LFGI-4USP AND LFGI-6USP

#### GENERAL NOTES

1. THIS OSHPD PRE APPROVAL OF MANUFACTURER'S CERTIFICATION (OPM) IS BASED ON THE CBC 2016. THE DEMAND (DESIGN FORCES) FOR USE WITH THIS OPM SHALL BE BASED ON THE CBC 2016.
2. THE DOCUMENT MAY ONLY BE USED WITH THE EXPRESS WRITTEN CONSENT OF THE MANUFACTURER LISTED ABOVE FOR A SPECIFIC PROJECT SITE AND INSTALLATION LOCATION. THE DOCUMENT IS INVALID WITHOUT SUCH CONSENT.
3. DESIGN CRITERIA AND LIMITATIONS:
  - A.  $S_{DS} \leq 1.5$  AND  $1.5 < S_{DS} \leq 2.5$
  - B.  $a_p = 1.0$
  - C.  $R_p = 2.5$
  - D.  $I_p = 1.5$
  - E.  $z/h = 0$ , FOR CONCRETE SLAB ON GRADE  
 $z/h \leq 1.0$ , FOR SLAB ABOVE GRADE
  - F.  $\Omega_o = 2.0$ , PER 2016 CBC 1616A.1.23 FOR CONCRETE ANCHORAGE
4. ALL ANCHOR FORCES SHOWN ON THIS DOCUMENT ARE STRENGTH LEVEL LOADS AND MAY BE USED FOR STRENGTH DESIGN.
5. THIS PRE APPROVAL COVERS ONLY THE SUPPORTS AND ATTACHMENTS OF EQUIPMENT TO THE STRUCTURE (CONCRETE SLAB OR CONCRETE TOPPING OVER METAL DECK WITH CONCRETE COMPRESSIVE STRENGTH,  $f'_c \geq 3000$  PSI, PER NOTE 3E)
6. SHEET METAL SCREWS (SMS) SHALL BE 18-8 STAINLESS STEEL SCREWS, ASTM A593D ( $F_y = 40$  KSI  $F_u = 80$  KSI).

#### RESPONSIBILITIES OF THE STRUCTURAL ENGINEER OF RECORD

1. VERIFY THAT THE INSTALLATION IS IN CONFORMANCE WITH THE 2016 CBC AND WITH THE DETAILS, MATERIAL AND GAGE OF THE UNIT WHERE ATTACHMENTS ARE MADE AGREE WITH THE INFORMATION SHOWN ON THE PREAPPROVAL DOCUMENTS.
2. VERIFY THAT THE PROJECT SPECIFIC VALUES OF  $S_{DS}$  AND  $z/h$  FOUND ON THE PREAPPROVAL DOCUMENTS ARE NOT EXCEEDED.
3. VERIFY THAT THE CONCRETE SLAB TO WHICH THE EQUIPMENT IS ANCHORED MEETS THE REQUIREMENTS OF THE APPLICABLE POST-INSTALLED ANCHOR ICC-ES EVALUATION REPORT.
4. VERIFY THAT THE POST-INSTALLED ANCHORS COMPLY WITH THE MINIMUM SPACING AND EDGE DISTANCE REQUIREMENTS DEFINED IN THE PREAPPROVAL DOCUMENT.
5. VERIFY THAT ALL NEW OR EXISTING ANCHORS ARE ADEQUATE DISTANCE FROM THE UNIT ATTACHMENTS AND CHECK FOR INTERACTION WHERE OTHER ANCHORS ARE WITHIN 18" OR  $6 \times h_{ef}$  FROM THE UNIT ANCHORS.
6. PROVIDE SUPPORT STRUCTURE DESIGNED TO SUPPORT WEIGHTS AND FORCES SHOWN IN ADDITION TO ALL OTHER LOADS. VERIFY THE ADEQUACY OF THE STRUCTURE THAT SUPPORTS THE EQUIPMENT FOR THE LOADS IMPOSED ON THEM BY THE EQUIPMENT IN ADDITION TO ALL OTHER LOADS.



SUN Structural Engineering, Inc.  
Consulting Structural Engineers



GERMFREE LABORATORIES  
COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR  
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LFGI-3USP, LFGI-4USP AND LFGI-6USP

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## POST-INSTALLED ANCHOR NOTES

1. POST-INSTALLED ANCHORS FOR ATTACHING THE EQUIPMENT TO SUPPORT STRUCTURE HILTI KWIK BOLT TZ STAINLESS STEEL (ICC-ES ESR-1917: REISSUED MAY 2017) AND SHALL COMPLY WITH THE FOLLOWING:

ANCHOR DIAMETER	CONCRETE TYPE	CONCRETE TYPE	MIN. EMBED. $h_{ef}$	MIN. SPACING	MIN. EDGE DIST.	MIN. CONC. THICKNESS	TORQUE TEST
1/2"	SAND LIGHT WT. OR NORMAL WT. ( $f_c' = 3000$ PSI MIN.)	SLAB-ON-GRADE OR ELEVATED SLAB	2"	6"	12"	4"	40 FT-LB

ANCHOR DIAMETER	CONCRETE TYPE	SLAB TYPE	MIN. EMBED. $h_{ef}$	MIN. SPACING	MIN. EDGE DIST.	MIN. CONC. THICKNESS	TORQUE TEST
1/2"	SAND LIGHT WT. OR NORMAL WT. ( $f_c' = 3000$ PSI MIN.)	SLAB-ON-METAL DECK	2"	12"	12"	3 1/4"	40 FT-LB

## TESTING OF POST-INSTALLED ANCHORS

2. TESTING OF EXPANSION ANCHOR BOLTS SHALL BE PER 2016 CBC, 1910A.5; TESTING SHALL BE DONE IN THE PRESENCE OF THE SPECIAL INSPECTOR AND REPORT OF THE TEST RESULTS SHALL BE SUBMITTED TO OSHPD,
- i) AFTER AT LEAST 24 HOURS HAVE ELAPSED SINCE INSTALLATION, TORQUE TEST AT LEAST 50% OF THE ANCHOR BOLTS.
- ii) ACCEPTANCE CRITERIA:
- TORQUE TEST: THE APPLICABLE TORQUE MUST BE ACHIEVED WITHIN THE 1/2 TURN OF THE NUT FOR WEDGE TYPE.
- iii) IF ANY ANCHOR FAILS, TEST ALL ANCHORS.
3. AVOID DAMAGING EXISTING STEEL REINFORCEMENT IN CONCRETE SLAB WHEN INSTALLING CONCRETE EXPANSION ANCHORS.
4. PROVIDE FOR FULL THREAD ENGAGEMENT OF NUT & WASHER.
- BOLTS THROUGH CONCRETE ON METAL DECK
5. BOLTS SHALL BE TORQUED BY 3/4" TURN OF NUTS AFTER SNUG TIGHT CONDITION IS ACHIEVED: SNUG-TIGHT CONDITION IS DEFINED AS THE TIGHTNESS REQUIRED TO BRING CONNECTED ELEMENTS INTO FIRM CONTACT.
6. HOLES DRILLED IN CONCRETE SLAB SHALL BE 1/16" LARGER THAN BOLT SIZE.
7. THROUGH-BOLTS IN CONCRETE SHALL RECEIVE SPECIAL INSPECTION AND TESTING (THROUGH-BOLTS WITH STEEL-TO-STEEL CONNECTION IN TENSION DO NOT REQUIRE TENSION TESTING) IN ACCORDANCE WITH REQUIREMENTS FOR POST-INSTALLED ANCHORS.

## WELDED STUDS

8. AFTER CABINET HEIGHT IS ADJUSTED TO THE DESIRED LEVEL, WELDED STUD NUT SHALL BE TIGHTENED TO 60 ft-lbs TORQUE.

## ATTACHMENT MATERIALS

9. ALL BENT STAINLESS STEEL PLATES & ANGLES: ASTM A240, TYPE 304,  $F_y = 30$  KSI  $F_u = 75$  KSI
10. ALL STRUCTURAL TUBES: ASTM A554, TYPE 304,  $F_y = 30$  KSI  $F_u = 75$  KSI
11. BOLTS & WELDED STUDS: ASTM F593D, TYPE 304,  $F_y = 40$  KSI  $F_u = 80$  KSI
12. BOLTS NUTS: ASTM F594D, TYPE 304
13. HARDENED PLAIN WASHER PLATES: ASTM A240 TYPE 304,  $F_y = 30$  KSI  $F_u = 75$  KSI
- ALL MEMBERS TO BE STAINLESS STEEL



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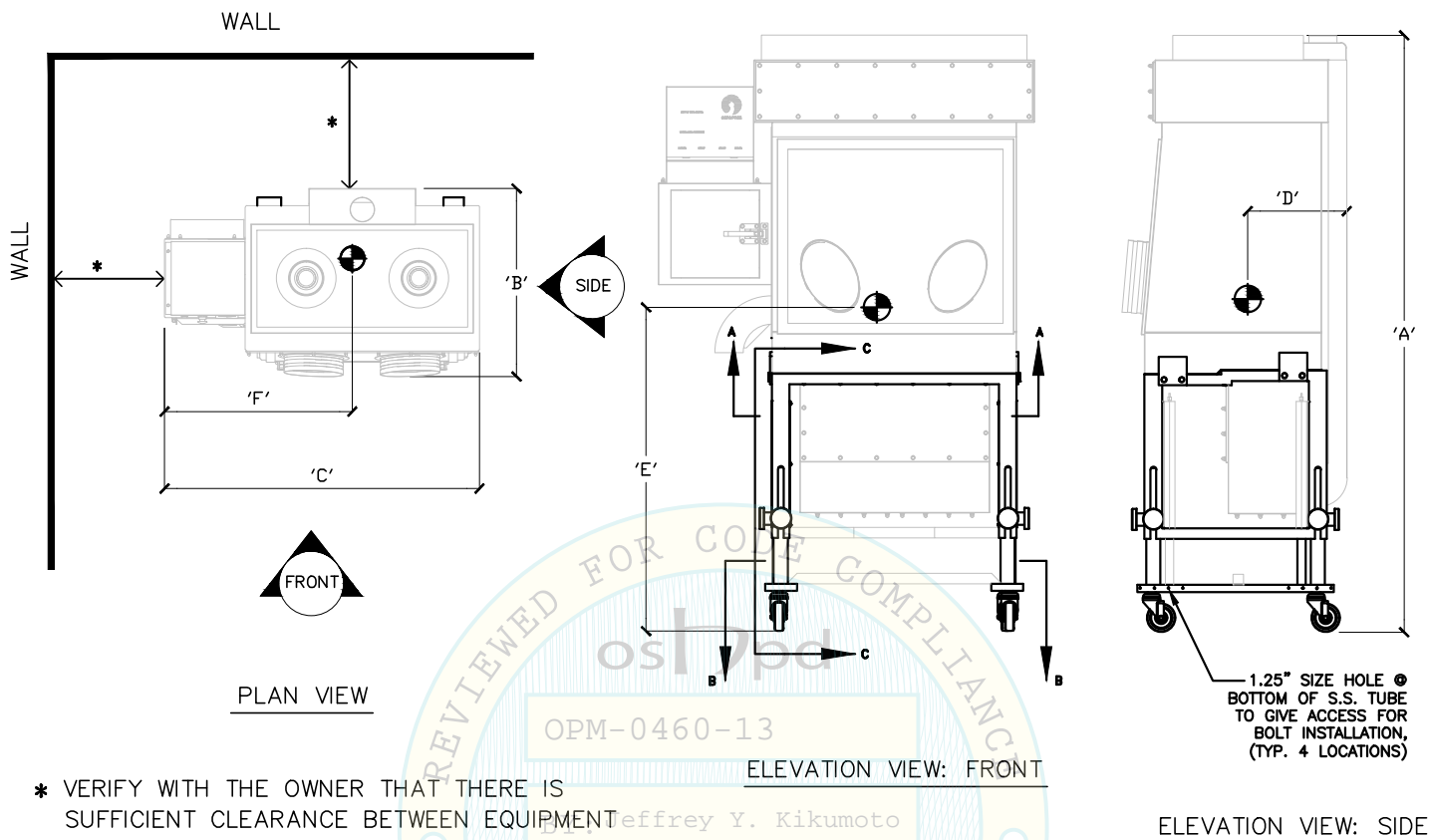
GERMFREE LABORATORIES  
COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR  
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LFGI-3USP, LFGI-4USP AND LFGI-6USP

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# ISOLATOR DIMENSIONS AND SCHEDULES



ISOLATOR TYPE	ISOLATOR DIMENSIONS AND CENTER OF GRAVITY						ISOLATOR WEIGHT
	A	B	C	D	E	F	
LFGI-3UPS	84.875"	30.75"	53.25"	13.5"	45.875"	19.75"	647 LBS
LFGI-4UPS	84.875"	30.75"	65.25"	13.5"	45.875"	25.75"	770 LBS
LFGI-6UPS	84.875"	30.75"	89.25"	13.5"	45.875"	37.75"	987 LBS



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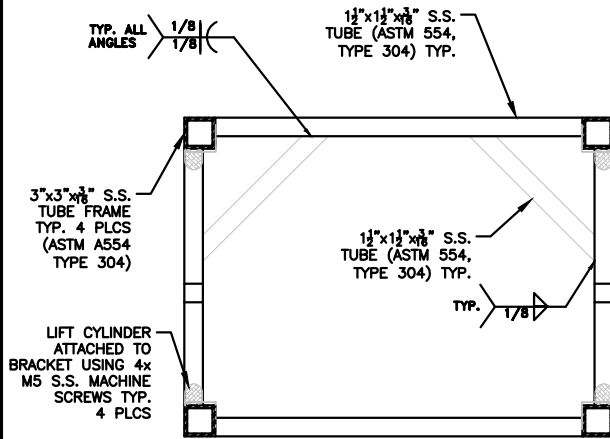
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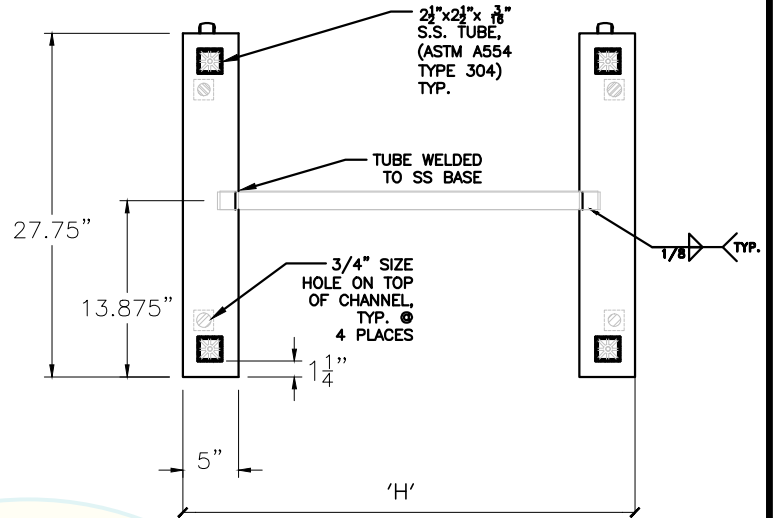
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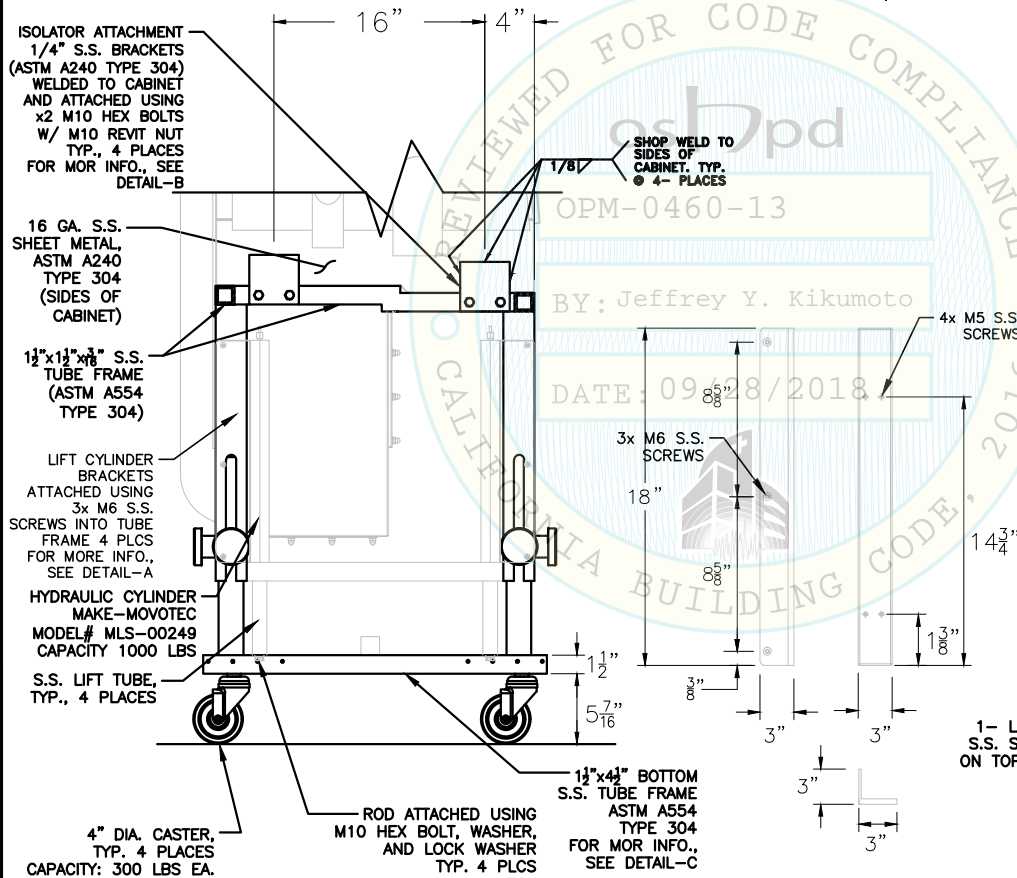
# ISOLATOR DETAILS



SECTION A-A



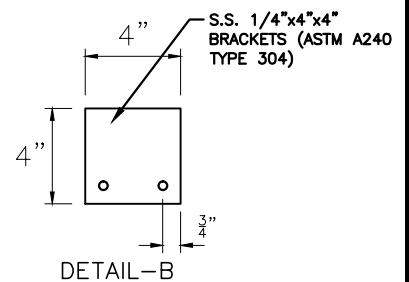
SECTION B-B



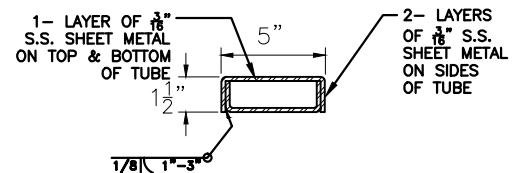
SECTION C-C

ISOLATOR TYPE	DIMENSIONS
	H
LFGI-3UPS	36.5"
LFGI-4UPS	48.5"
LFGI-6UPS	72.5"

DETAIL-A



DETAIL-B



DETAIL-C



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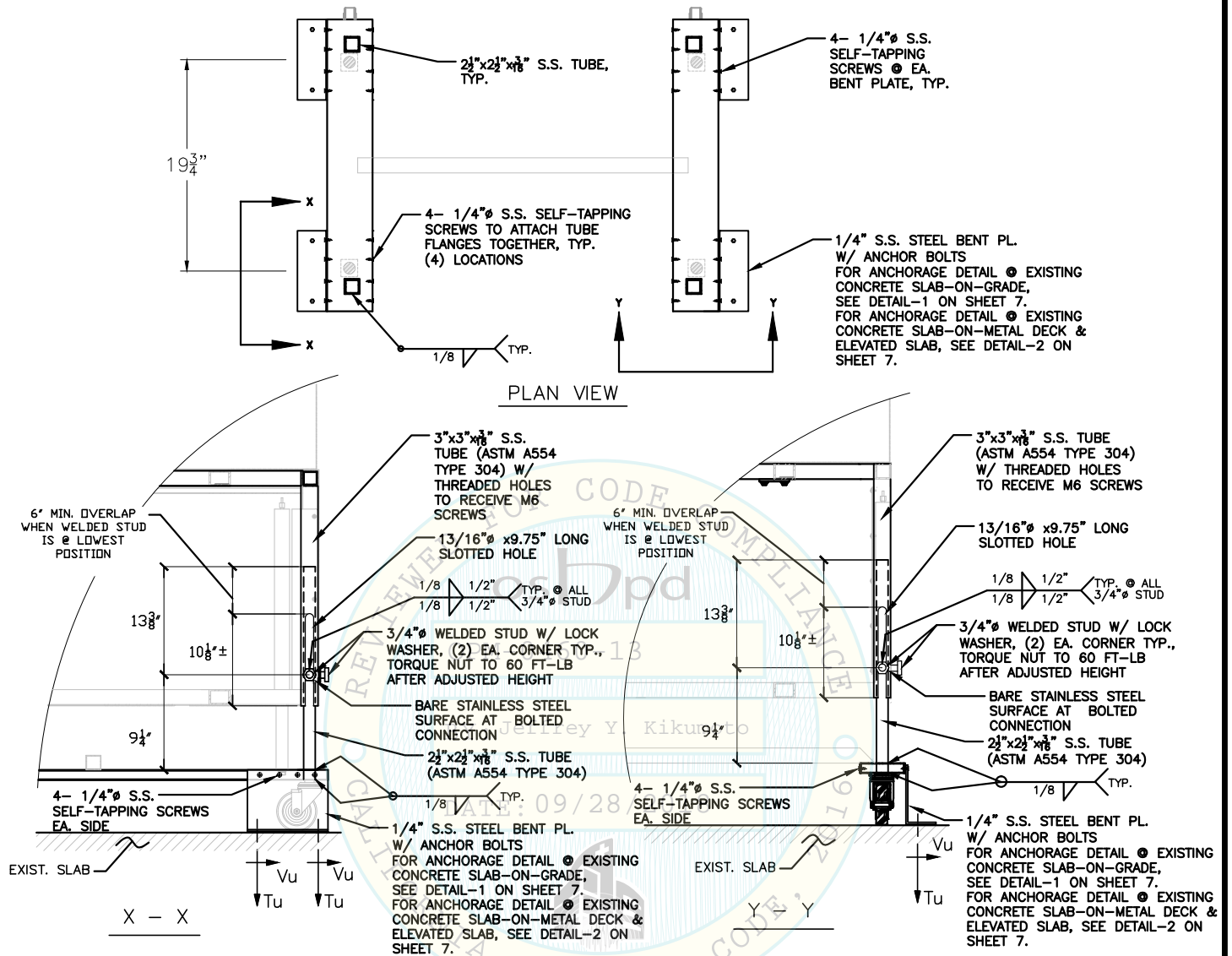
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# ISOLATOR SUPPORTS AND ATTACHMENT FORCES AND DETAILS (FOR $S_{DS} \leq 1.5$ )



ISOLATOR TYPE	ANCHORAGE VERTICAL (UPLIFT, $T_u$ ) AND HORIZONTAL (SHEAR, $V_u$ ) REACTIONS AT INTERFACE WITH CONCRETE SLAB (STRENGTH DESIGN)			
	$z/h=0$ , $S_{DS} \leq 1.5$		$z/h \leq 1.0$ , $S_{DS} \leq 1.5$	
	$T_u$ /BOLT (LBS)	$V_u$ /BOLT (LBS)	$T_u$ /BOLT (LBS)	$V_u$ /BOLT (LBS)
LFGI-3UPS	808	142	632	227
LFGI-4UPS	929	169	725	271
LFGI-6UPS	1146	217	893	347



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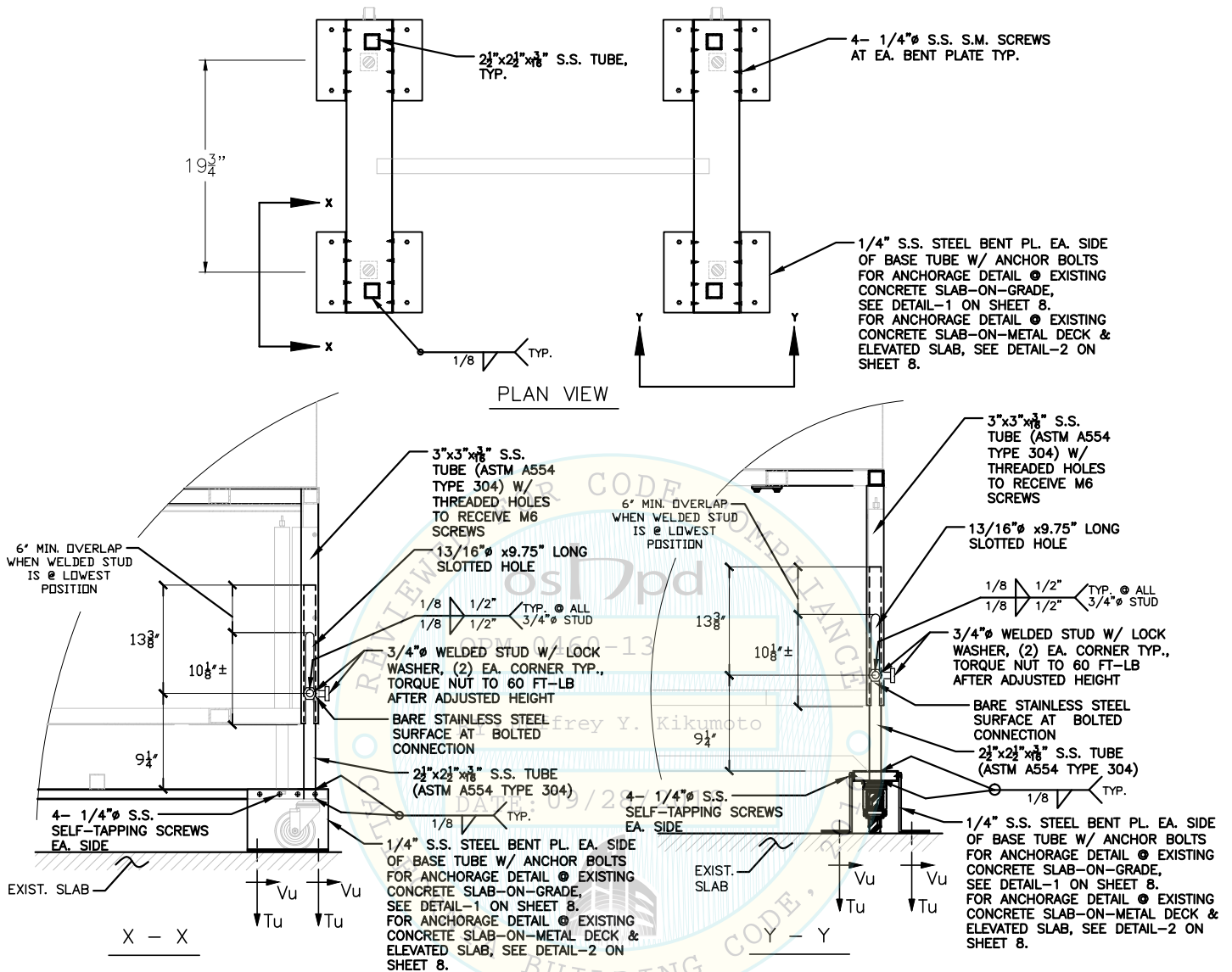
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# ISOLATOR SUPPORTS AND ATTACHMENT FORCES AND DETAILS (FOR $1.5 < S_{DS} \leq 2.5$ )



ANCHORAGE VERTICAL (UPLIFT,  $T_u$ ) AND HORIZONTAL (SHEAR,  $V_u$ ) REACTIONS AT INTERFACE WITH CONCRETE SLAB (STRENGTH DESIGN)

CABINET TYPE	$z/h=0, 1.5 < S_{DS} \leq 2.5$		$z/h \leq 1.0, 1.5 < S_{DS} \leq 2.5$	
	$T_u$ /BOLT (LBS)	$V_u$ /BOLT (LBS)	$T_u$ /BOLT (LBS)	$V_u$ /BOLT (LBS)
LFGI-3UPS	731	119	579	190
LFGI-4UPS	828	141	657	226
LFGI-6UPS	1016	181	806	289



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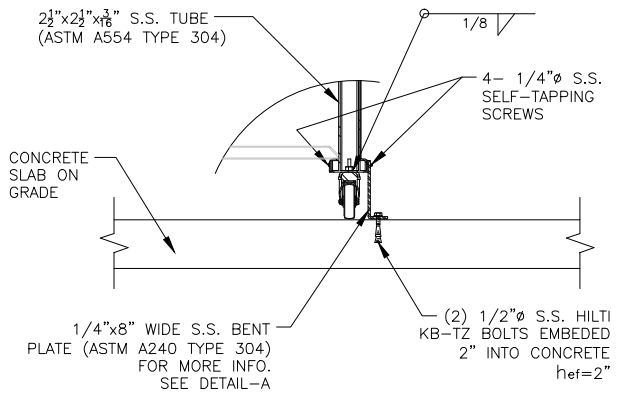
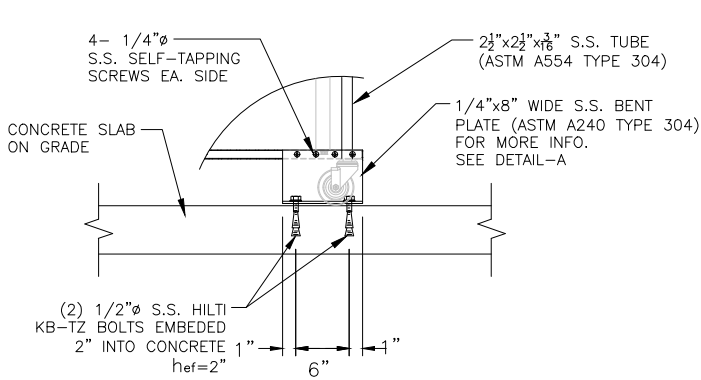
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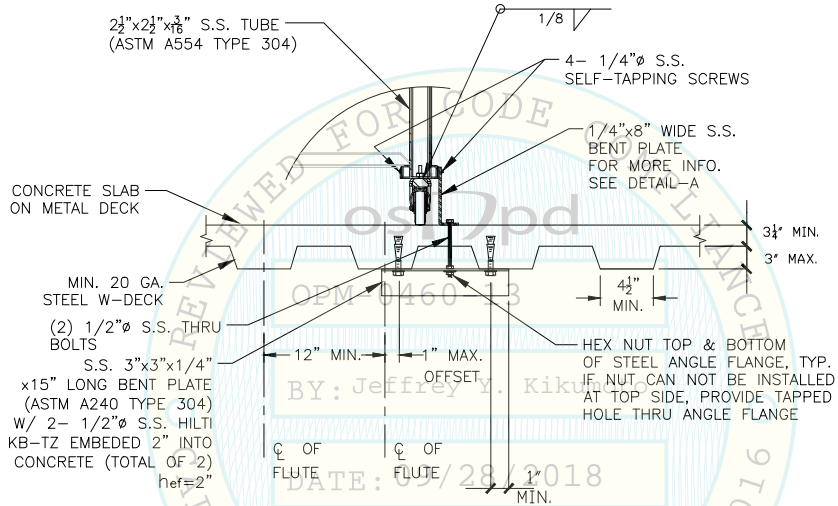
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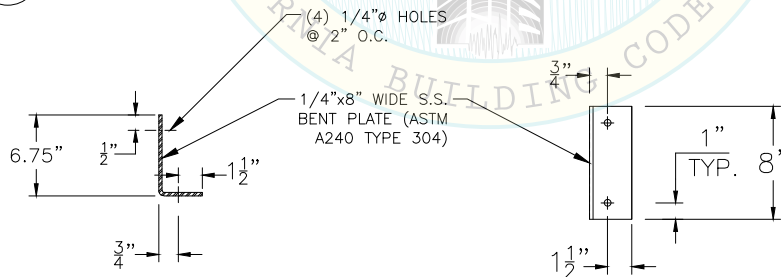


ISOLATOR SUPPORTS AND ATTACHMENT DETAILS (FOR  $S_{DS} \leq 1.5$ )

1 ANCHORAGE TO CONCRETE SLAB-ON-GRADE WITH 4" MIN. THICKNESS



## 2 ANCHORAGE TO CONCRETE SLAB ON METAL DECK



ELEVATION VIEW

PLAN VIEW

A STEEL BENT PLATE DETAIL



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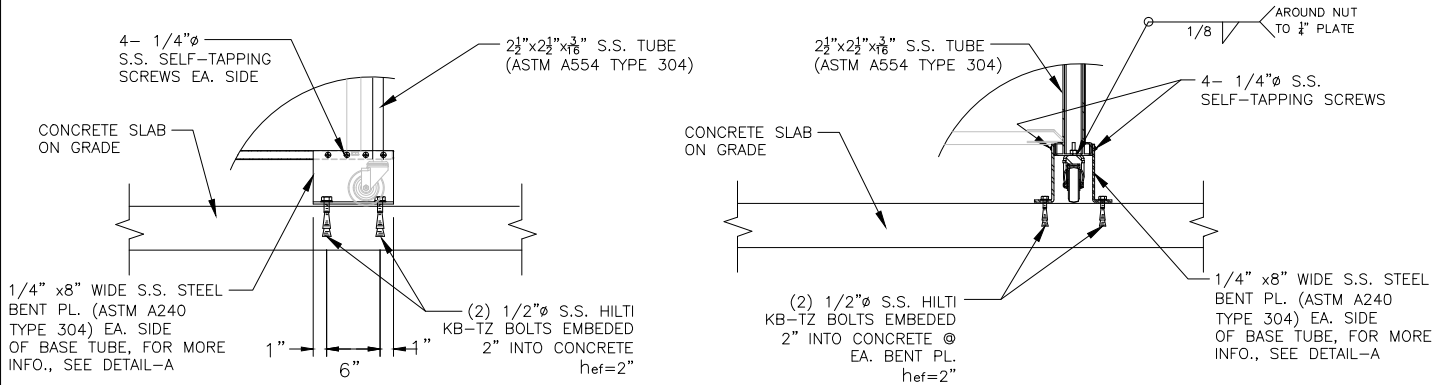
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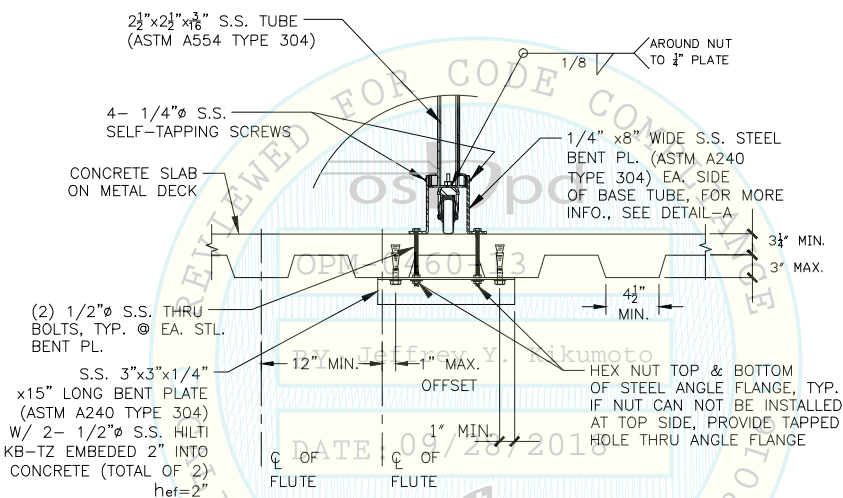
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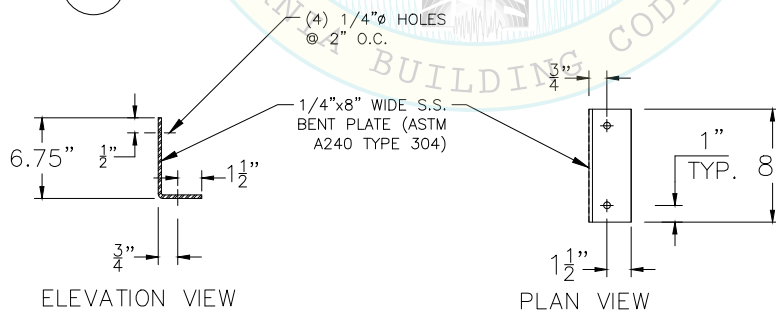
# ISOLATOR SUPPORTS AND ATTACHMENT DETAILS (FOR $1.5 < S_{DS} \leq 2.5$ )



## 1 ANCHORAGE TO CONCRETE SLAB-ON-GRADE WITH 4" MIN. THICKNESS



## 2 ANCHORAGE TO CONCRETE SLAB ON METAL DECK



## A STEEL BENT PLATE DETAIL



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