BIOZEEN®

We are into the business of Saving Lives

Types of stainless steel and welding controls applied in the pharmaceutical industry for product-contact areas.

18.07.19

Agenda

- Biozeen Introduction
- Stainless Steel
- Types of Stainless Steel used in biopharmaceutical industry
- Selection of the Stainless Steel
- Welding in bioprocess equipment & Welding Management System
- Controlling welding
- Welding Documentation

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PEP-PROCESS, EQUIPMENT, PEOPLE

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Bioreactor systems
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Bio-Kill systems
Sanitary Vessels
Crystallizers
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- Plant Automation
- PLC Programming
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- Process Optimization
- Contamination trouble shooting
- Process Validation
- Project Management

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- Efficiency Improvement studies
- Glycosylation
- Perfusion with micro carriers
- Algae culture
- High cell density of VERO / CHO cell lines

Manpower Training

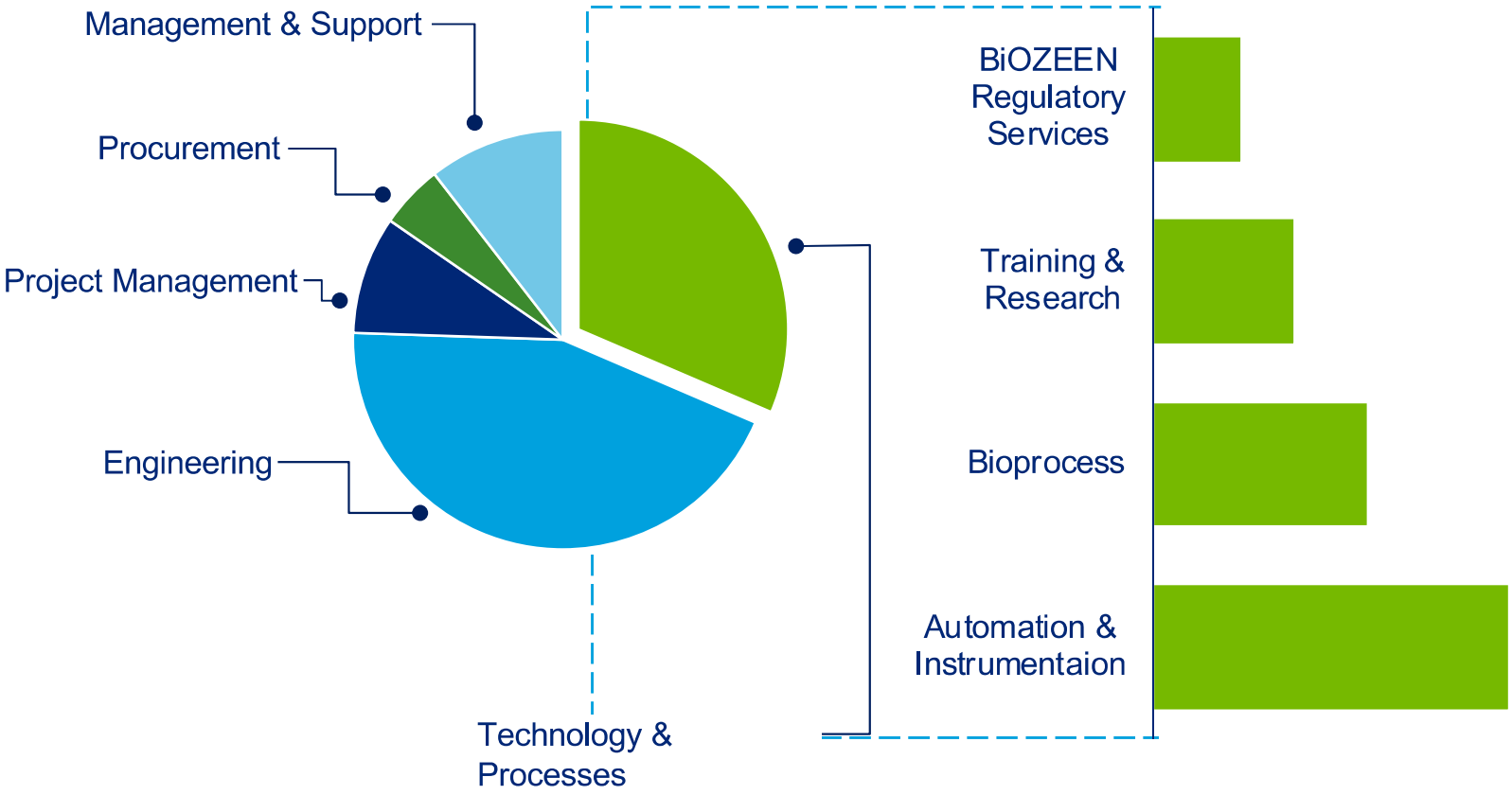
- Fermentation Technology
- Mammalian Cell Culture Technology
- Downstream Processing
- Sterilization & Filtration Technology
- Bioprocess Engineering
- Regulatory Aspects & Documentation

BiOZEEN Regulatory Services

- Filter Train Optimization Study
- Compatibility Study
- Product based Integrity Study
- Bacterial Retention Study
- Protein & Preservative Binding Study

BiOZEENites

Head Quarters: Bangalore | **Employees**: 225 | **Number of Business Lines**: 6 | **Number of Product Lines**: 8



BiOZEEN DESIGN & BUILD INFRASTRUCTURE

Manufacturing Workshop

- Campus spread across 4 Hectares
- Floor area of 35,000 Sq. ft
- Executed Bioreactor/ Fermenter from 1L to 10000L
- In-house facility for electro polishing

- State-of-the-art Quality Control Units
- Clean and Black utilities
- Boilers, Chillers, Compressors, WFI generators

Integrated FAT centre

BiOZEEN Facility Layout

BiOZEEN DESIGN & BUILD INFRASTRUCTURE

Manufacturing Workshop

- State-of-the-art New Manufacturing Centre located in Hardware Park, Bangalore, India
- Floor area of 50,000 Sq. ft
- Operational since June 2018

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Stainless Steel

Stainless Steel

The date was June 4, 1912

Harry Brearley was in charge of the Brown-Firth Research Laboratory in Sheffield, England.

The Brown-Firth Research laboratories in Princess Street, Sheffield, where Brearley discovered Stainless Steel

While the lab was investigating ways to eliminate rust in gun barrels, Mr. Brearley noticed that a discarded steel sample from an earlier test was not rusting while the other samples rusted.

Two months later, on August 20, 1912, stainless steel was cast for the first time

Stainless Steel

Even though many people were involved in finding Stainless Steel, records consider Mr. Brearley as the inventor of Stainless Steel !

(No work is done without documentation)

A NON-RUSTING STEEL.

Sheffield Invention Especially Good for Table Cutlery.

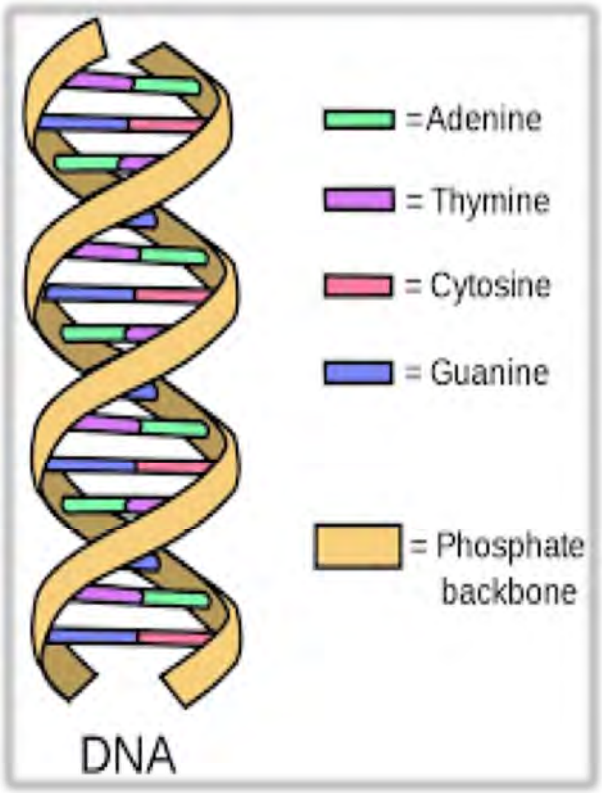
According to Consul John M. Savage, who is stationed at Sheffield, England, a firm in that city has introduced a stainless steel, which is claimed to be non-rusting, unstainable, and untarnishable. This steel is said to be especially adaptable for table cutlery, as the original polish is maintained after use, even when brought in contact with the most acid foods, and it requires only ordinary washing to cleanse.

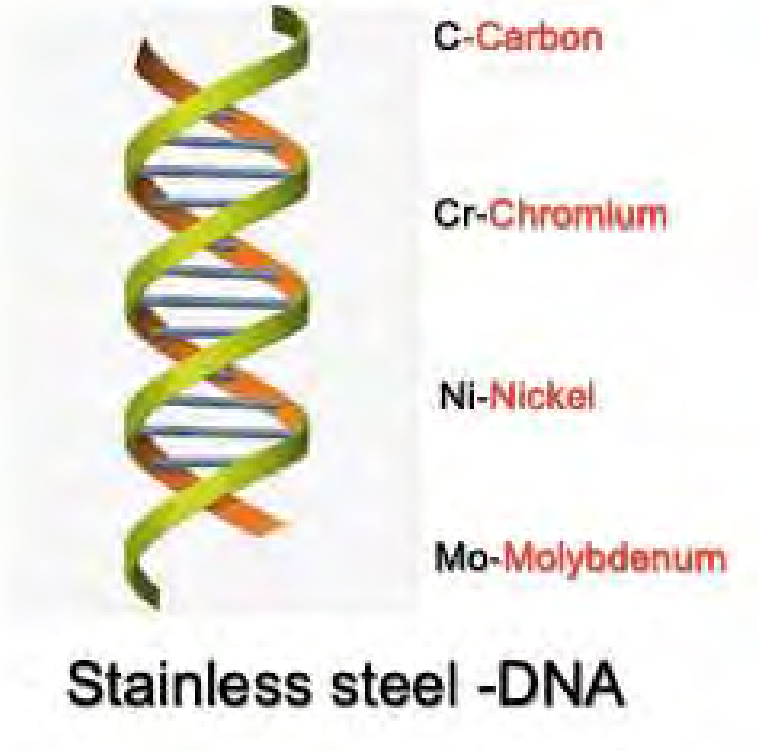
"It is claimed," writes Mr. Savage in the Commerce Reports, "that this steel retains a keen edge much like that of the best double-sheer steel, and, as the properties claimed are inherent in the steel and not due to any treatment, knives can readily be sharpened on a steel or by using the ordinary cleaning machine or knifeboard. It is expected it will prove a great boon, especially to large users of cutlery, such as hotels, steamships, and restaurants.

"The price of this steel is about 26 cents a pound for ordinary sizes, which is about double the price of the usual steel for the same purpose. It also costs more to work up, so that the initial cost of articles made from this new discovery, it is estimated, will be about double the present cost; but it is considered that the saving of labor to the customer will more than cover the total cost of the cutlery in the first twelve month."

Types of Stainless Steel

Today, there are 200 types of Stainless steels available.





As these 4 elements change,

- Type of stainless steel change
- Composition Changes
- Properties Changes

Types of Stainless Steel

- **Austenitic:** High Chromium and Nickel content of the grades in this group provide superior corrosion resistance and very good mechanical properties (eg: 304, 304L,316, 316L)
- **Super austenitic:** A subgroup of austenitic stainless steels. Having elevated levels of nickel, chromium, and molybdenum compared with standard austenitic stainless steels. May have other additions (e.g., nitrogen and/or copper) to increase strength and resistance to pitting corrosion and stress corrosion cracking in the presence of chlorides. (eg: 904L(N08904), 6MO/254 SMO (S 31254), AL-6XN (N08367)
- **Ferritic:** A higher corrosion resistance than martensitic grades, but are mostly inferior to the austenitic grades. These grades are straight Chromium steels with no Nickel (eg: 409, 405,430, 444)

Types of Stainless Steel

- **Martensitic**: A group of stainless alloys made to be corrosion resistant and hardenable (using heat treating). Chromium steels without nickel. Used where hardness, strength, and wear resistance are required like filter holder support and cross flow filter bars etc. (eg: 410, 420,440A, 440C)
- **Duplex :** Duplex grades are a combination of austenitic and ferritic material. Twice as strong as the austenitic and ferritic grades. Better toughness and ductility than the ferritic grades, they do not reach the levels of the austenitic grades. Duplex grades have a corrosion resistance very close to the austenitic grades such as 304 and 316. Grade 2205 is the most widely used in the duplex class
- **Precipitation hardening** : Precipitation hardening stainless steel can be strengthened and hardened by heat treatment. This offers the designer a unique combination of fabric-ability, strength, ease of heat treatment, and corrosion resistance not found in any other class of material. These grades include 17Cr-4Ni (17-4PH) and 15Cr-5Ni (15-5PH)

Types of Stainless Steel

Table 1: Austenitic Stainless Steel Chemical Compositions (Weight Percent)

Austenitic Stainless Steels									
Common Name	UNS No.	C	Cr	Ni	Mo	N	Mn	Cu	Other
201	S20100	0.15	16.0-18.0	3.5-5.5	-	0.25	5.50-7.50	-	-
301	S30100	0.15	16.0-18.0	6.0-8.0	-	0.10	2.00	-	-
304L	S30403	0.030	17.5-19.5	8.0-12.0	-	0.10	2.00	-	-
305	S30500	0.12	17.0-19.0	10.5-13.0	-	-	2.00	-	-
321	S32100	0.08	17.0-19.0	9.0-12.0	-	0.10	2.00	-	Ti 5x(C+N)
347	S34700	0.08	17.0-19.0	9.0-13.0	-	-	2.00	-	Cb 10xC to 1.00
309S	S30908	0.08	22.0-24.0	12.0-15.0	-	-	2.00	-	-
310S	S31008	0.08	24.0-26.0	19.0-22.0	-	-	2.00	-	-
316L	S31603	0.030	16.0-18.0	10.0-14.0	2.00-3.00	0.10	2.00	-	-
317L	S31703	0.030	18.0-20.0	11.0-15.0	3.0-4.0	0.10	2.00	-	-
317LMN	S31726	0.030	17.0-20.0	13.5-17.5	4.0-5.0	0.10-0.20	2.00	-	-
904L	N08904	0.020	19.0-23.0	23.0-28.0	4.00-5.00	0.10	2.00	1.00-2.00	-

Types of Stainless Steel

Table 2: Common Ferritic Stainless Steel Chemical Compositions (Weight Percent)

Ferritic Stainless Steels									
Common Name	UNS No.	C	Cr	Ni	Mo	N	Mn	Cu	Other
409	S40910	0.030	10.5-11.7	0.50	-	0.030	1.00	-	Ti 6x(C+N) to .50 Cb 0.17
	S40920	0.030	10.5-11.7	0.50	-	0.030	1.00	-	Ti 8x(C+N) min. Ti 0.15-0.50 Cb 0.10
	S40930	0.030	10.5-11.7	0.50	-	0.030	1.00	-	(Ti+Cb) [0.08+8x(C+N)] to 0.75 Ti 0.05 min.
405	S40500	0.08	11.5-14.5	0.60	-	-	1.00	-	Al 0.10-0.30
430	S43000	0.12	16.0-18.0	0.75	-	-	1.00	-	-
434	S43400	0.12	16.0-18.0	-	0.75-1.25	-	1.00	-	-
436	S43600	0.12	16.0-18.0	-	0.75-1.25	-	1.00	-	Cb 5xC to 0.80
439	S43035	0.030	17.0-19.0	0.50	-	0.030	1.00	-	Ti [0.20+4(C+N)] to 1.10 Al .15 max.
444	S44400	0.025	17.5-19.5	1.00	1.75-2.50	0.035	1.00	-	(Ti+Cb) [0.20+4(C+N)] to 0.80 max.
26-3-3	S44660	0.030	25.0-28.0	1.0-3.5	3.0-4.0	0.040	1.00	-	(Ti+Cb) 0.20 to 1.00 and (Ti+Cb) 6x(C+N) min.

Types of Stainless Steel

Table 3: Common Martensitic Stainless Steel Chemical Compositions (Weight Percent)

Martensitic Stainless Steels									
Common Name	UNS No.	C	Cr	Ni	Mo	N	Mn	Cu	Other
410	S41000	0.08-0.15	11.5-13.5	0.75	-	-	1.00	-	-
420	S42000	0.15 min.	12.0-14.0	0.75	0.50	-	1.00	-	-
440A	S44002	0.60-0.75	16.0-18.0	-	0.75	-	1.00	-	-
440C	S44004	0.95-1.20	16.0-18.0	-	0.75	-	1.00	-	-

Types of Stainless Steel

Table 4: Common Precipitation Hardening Stainless Steel Chemical Compositions (Weight Percent)

Precipitation Hardening Stainless Steels									
Common Name	UNS No.	C	Cr	Ni	Mo	N	Mn	Cu	Other
XM-13	S13800	0.05	12.3-13.2	7.5-8.5	2.00-2.50	0.01	0.20	-	Al 0.90-1.35
XM-12	S15500	0.07	14.0-15.5	3.5-5.5	-	-	1.00	2.5-4.5	Cb+Ta 0.15-0.45
632	S15700	0.09	14.0-16.0	6.5-7.7	2.00-3.00	-	1.00	-	Al 0.75-1.50
630	S17400	0.07	15.0-17.5	3.0-5.0	-	-	1.00	3.0-5.0	Cb+Ta 0.15-0.45
631	S17700	0.09	16.0-18.0	6.5-7.7	-	-	1.00	-	Al 0.75-1.50

Types of Stainless Steel

Table 5: Common Duplex Stainless Steel Chemical Compositions (Weight Percent)

Duplex Stainless Steels									
Common Name	UNS No.	C	Cr	Ni	Mo	N	Mn	Cu	Other
	S31200	0.030	24.0-26.0	5.5-6.5	1.20-2.00	0.14-0.20	2.00	-	-
	S31260	0.030	24.0-26.0	5.5-7.5	2.5-3.5	0.10-0.30	1.00	0.20-0.80	W 0.10-0.50
	S32001	0.030	19.5-21.5	1.00-3.00	0.60	0.05-0.17	4.0-6.0	1.00	-
	S32003	0.030	19.5-22.5	3.0-4.0	1.50-2.00	0.14-0.20	2.00	-	-
	S32101	0.040	21.0-22.0	1.35-1.70	0.10-0.80	0.20-0.25	4.0-6.0	0.10-0.80	-
	S32202	0.030	21.5-24.0	1.00-2.80	0.45	0.18-0.26	2.00	-	-
2304	S32304	0.030	21.5-24.5	3.0-5.5	0.05-0.60	0.05-0.20	2.50	0.05-0.60	-
2205	S31803	0.030	21.0-23.0	4.5-6.5	2.5-3.5	0.08-0.20	2.00	-	-
2205	S32205	0.030	22.0-23.0	4.5-6.5	3.0-3.5	0.14-0.20	2.00	-	-
	S32506	0.030	24.0-26.0	5.5-7.2	3.0-3.5	0.08-0.20	1.00	-	W 0.05-0.30
	S32520	0.030	24.0-26.0	5.5-8.0	3.0-4.0	0.20-0.35	1.50	0.50-2.00	-
255	S32550	0.04	24.0-27.0	4.5-6.5	2.9-3.9	0.10-0.25	1.50	1.50-2.50	-
2507	S32750	0.030	24.0-26.0	6.0-8.0	3.0-5.0	0.24-0.32	1.20	0.50	-
	S32760	0.030	24.0-26.0	6.0-8.0	3.0-4.0	0.20-0.30	1.00	0.50-1.00	W 0.50-1.00
	S32808	0.030	27.0-27.9	7.0-8.2	0.8-1.2	0.30-0.40	1.10	-	W 2.10-2.50
	S32906	0.030	28.0-30.0	5.8-7.5	1.50-2.60	0.30-0.40	0.80-1.5	0.80	-
	S32950	0.030	26.0-29.0	3.50-5.20	1.00-2.50	0.15-0.35	2.00	-	-
	S39274	0.030	24.0-26.0	6.8-8.0	2.5-3.5	0.24-0.32	1.0	0.20-0.80	W 1.50-2.50
	S82011	0.030	20.5-23.5	1.0-2.0	0.10-1.00	0.15-0.27	2.0-3.0	0.50	-

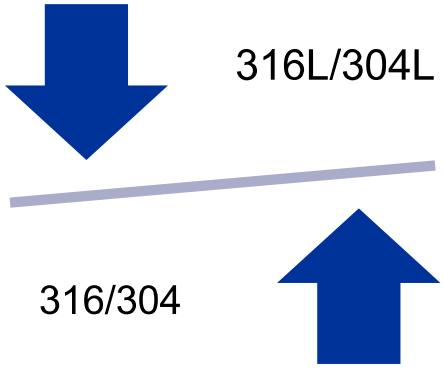
Types of Stainless Steel

Summary of the main advantages of the stainless steel types

Type	Examples	Advantages	Disadvantages
Ferritic	410S, 430, 446	Low cost, moderate corrosion resistance & good formability	Limited corrosion resistance, formabilty & elevated temperature strength compared to austenitics
Austenitic	304,316	Widely available, good general corrosion resistance, good cryogenic toughness. Excellent formability & weldability	Work hardening can limit formability & machinability. Limited resistance to stress corrosion cracking
Duplex	1.4462	Good stress corrosion cracking resistance, good mechanical strength in annealed condition	Application temperature range more restricted than austenitics
Martensitics	420, 431	Hardenable by heat treatment	Corrosion resistance compared to austenitics & formability compared to ferritics limited. Weldability limited
Precipitation hardening	17/4PH	Hardenable by heat treatment, but with better corrosion resistance than martensitics	Limited availability, corrosion resistance, formability & weldability restricted compared to austenitics

Types of Stainless Steel – Product Contact

- **Type 316:**
- 18% chromium, 14% Nickel and added Molybdenum
- In combination increase its resistance to corrosion.
- In particular, molybdenum helps to control the pit type attack of corrosion.
- The “L” grades provide extra corrosion resistance **after welding**. (Carbon levels are kept to .03%)



Types of Stainless Steel – Product Contact Surface

- **Type 316L (1.4435):**

  Slightly higher

- (17.0to19.0%) chromium,
- (12.5 to 13.5% Nickel) and
- (2.5 to 3.0%) Molybdenum.
- This grade stainless steel helps in control of delta control at the welding area.
- (outcome of the Basler Norm 2 that tried to reduce concerns of rouging)

Select the Right Stainless Steel

How do we select the right one for our application?

- Corrosive environment : Atmospheric, water, concentration of particular chemicals, chloride content, presence of acid
- Temperature
- Strength Required
- Metal Joining Process Required
- Degree of Forming Required
- Product Form Required
- Surface Finish Required
- Cost

When in doubt, please share the process details & chemicals that come in contact to the manufacturer to check the compatibility.

Stainless Steel Welding

Stainless Steel Welding

For pressure vessels, tanks, piping and tubing systems where the process contact surface of the weld is to be used “As is”,

- welding processes shall be limited to the inert-gas arc processes (such as gas tungsten-arc welding and plasma arc welding)
- the high energy beam processes (such as electron beam or laser beam welding), as defined in AWS A3.0

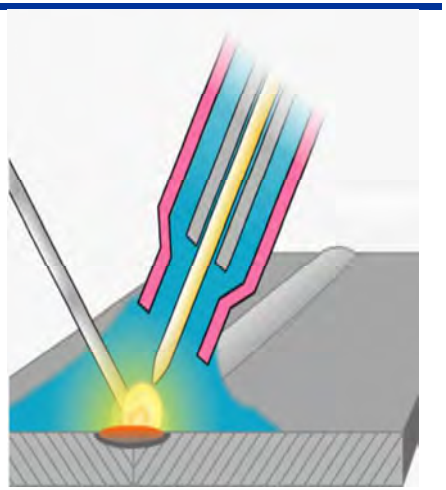
Gas Tungsten Arc Welding

Joining of metal by placing an arc in between the metals

Shielding with an inert gas or mixture.

With or without filler material

Manual or automatic (orbital welding)



Welding

Weld Controlling

S-Sulphur control in Steel

O-Oxygen control in Welding Gas

F-Ferrite control in Steel

T-Tungsten control in process

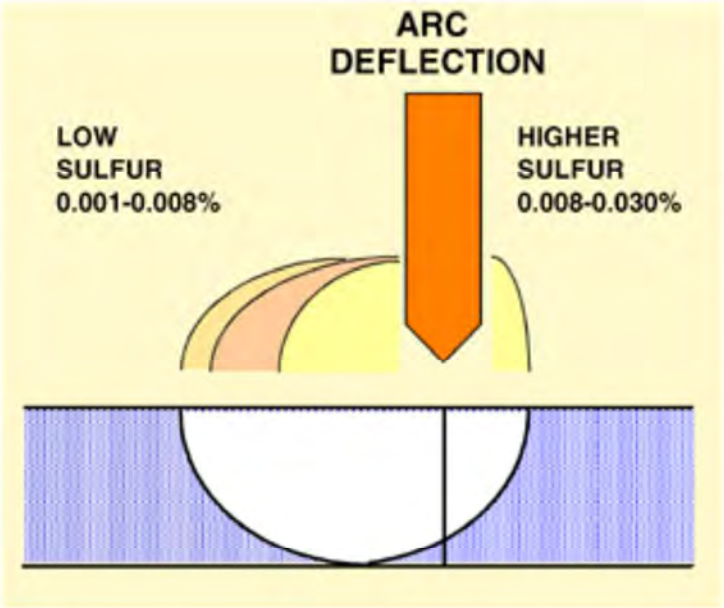
Weld Controlling - Sulphur

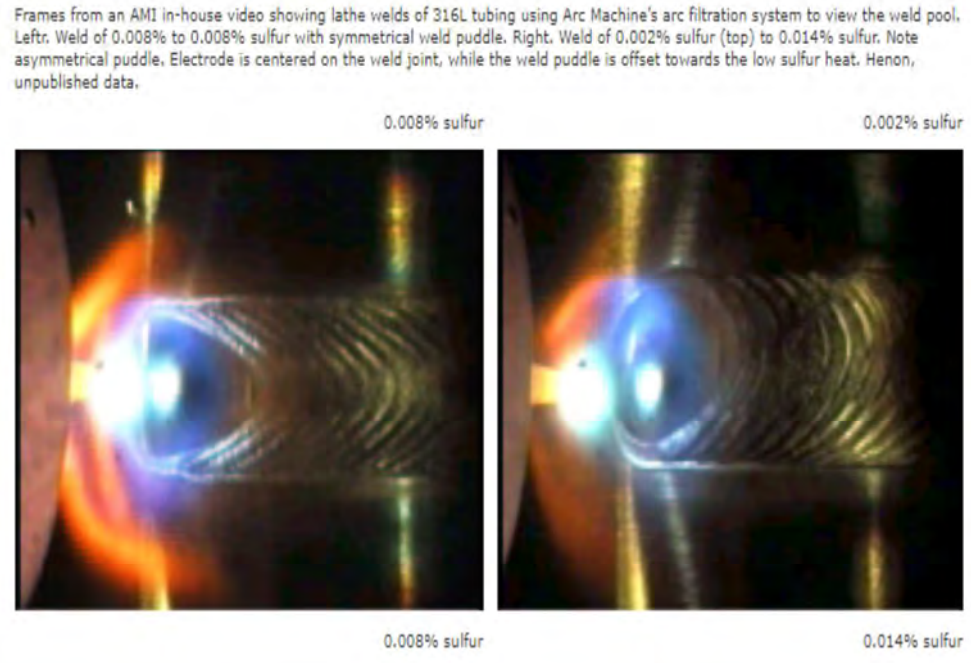
MM-5.2.1.1 Weld Ends.

Weld ends that are to be automatically welded shall have a Sulphur content between 0.005 wt. % and 0.017 wt. %

This requirement applies to the austenitic stainless steels

This requirement does not apply to materials used in the construction of process components, only to the weld ends of process components in their final form.

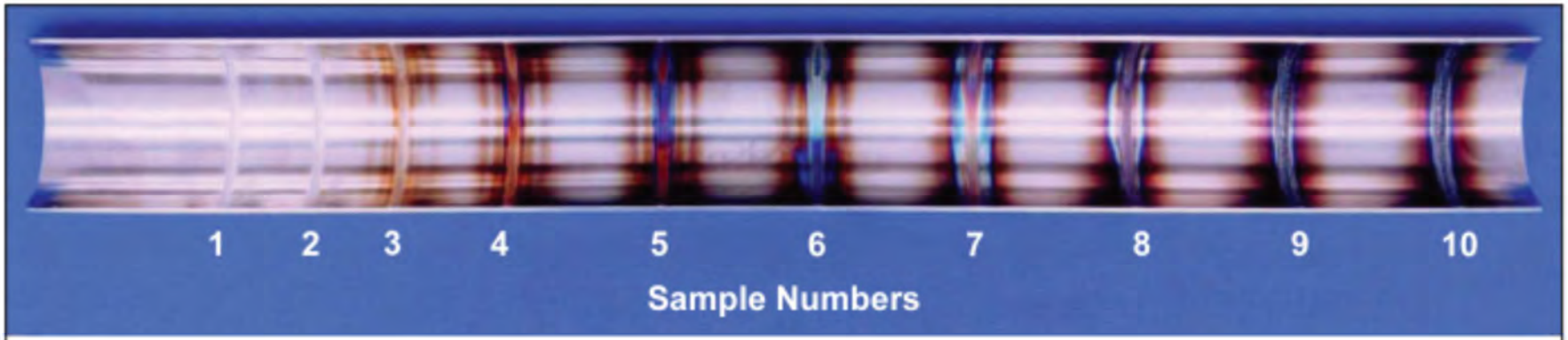




Weld Controlling - Sulphur

Weld Controlling - Oxygen

Oxygen contamination during welding leads to Discoloration and corrosion!



Notes:

1. The tube sample was prepared by making ten autogenous welds on the outside diameter of a 2 in. (50.8 mm) 316L stainless steel tube. Welds on 304L tubing showed no significant difference in heat tint from 316L. The welds were full penetration welds. The torch shielding gas was 95% argon, 5% hydrogen [99.998 with <2 parts per million (ppm) of oxygen, moisture, and hydrocarbons] to assure full penetration welds. The hydrogen addition to the torch shielding gas is considered to have no effect on the HAZ heat-tint oxide on the inside surface. To provide varying amounts of oxygen in the backing gas a compressed cylinder of medical grade air was added to 99.98% minimum pure argon (<2 ppm of oxygen, moisture, and hydrocarbons) and the oxygen was measured with a calibrated commercial oxygen indicator. The amount of oxygen in ppm in the backing gas was measured to be as follows:

No. 1–10	No. 3–50	No. 5–200	No. 7–1000	No. 9–12500
No. 2–25	No. 4–100	No. 6–500	No. 8–5000	No. 10–25000

2. The illustration should be used as a reference to identify the degree of heat-tint oxide by number and not to specify oxygen limits in the backing gas. The acceptable degree of heat tint can vary with different service environments. It should be considered along with the economics involved obtaining very low levels of heat tint when specifying acceptable heat tint level welds.

   The amount and visual appearance of heat-tint oxide can be influenced by factors other than oxygen, such as:

   - High levels of moisture in the backing gas will increase the degree of heat-tint.
   - Contaminates such as hydrocarbons, moisture, and some types of particulate on the surface prior to welding can influence heat-tint oxide levels.
   - Hydrogen gas in the argon backing gas can significantly reduce the amount of heat-tint oxide.
   - The metal surface finish can have a varying affect on the visual appearance of heat tint.

Figure 10. AWS D18.2 weld discoloration chart.

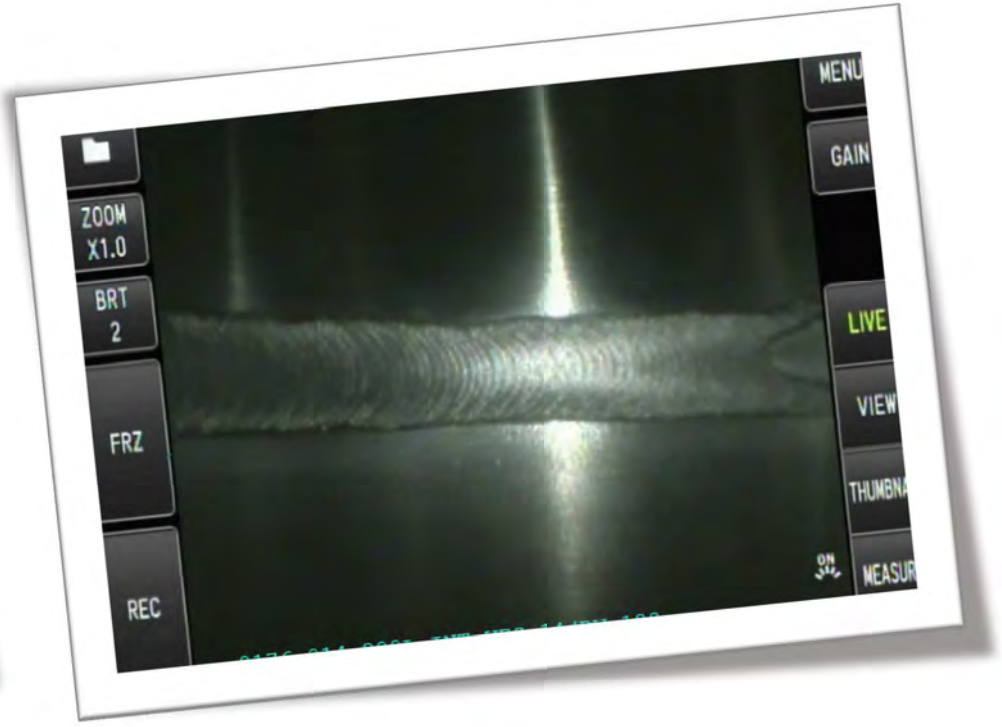
Weld Controlling - Oxygen

Oxygen contamination during welding leads to Discoloration and corrosion!

Weld Controlling - Oxygen

Oxygen contamination during welding leads to Discoloration and corrosion!

Without Oxygen Monitoring



With Oxygen Monitoring

Weld Controlling – Delta ferrite

Ferrite is a phase that may precipitate during solidification of austenitic stainless steel depending on the ratios of the alloying elements.

The presence of ferrite in austenitic stainless steel welds may reduce the corrosion resistance in some corrosive environments.

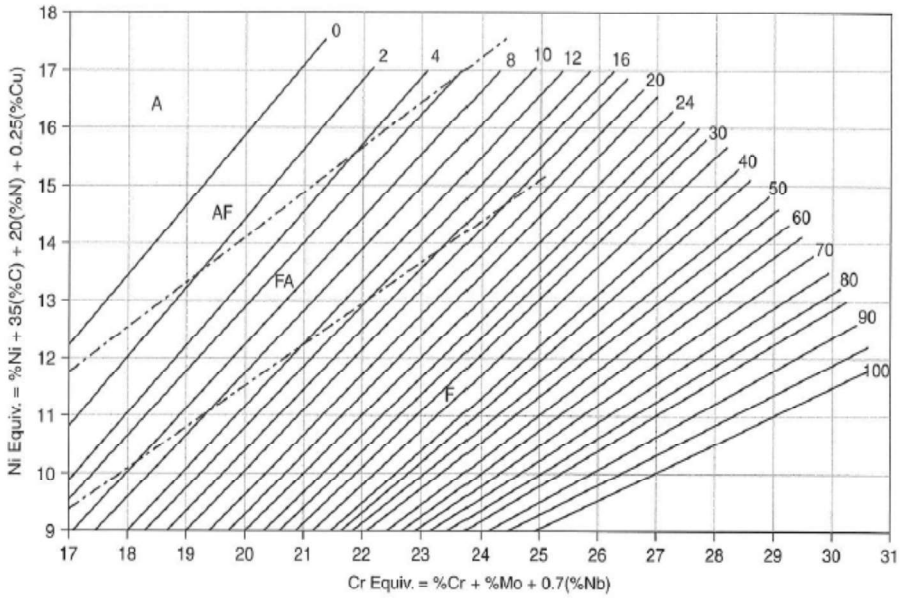
However, a minimum ferrite level may be required to maintain specific properties of particular product forms (e.g., castings) or is deemed necessary to prevent hot cracking of heavy wall weldments (e.g., vessels made from plate).

The ferrite level of as-solidified austenitic stainless steel welds can be determined from the WRC-1992 Constitution Diagram for Stainless Steel Weld Metals using

- Chromium equivalent Cr (eq) p %Cr + %Mo + 0.7%Nb and
- Nickel equivalent Ni (eq) p%Ni + 35%C + 20%N + 0.25%Cu.

Measuring of ferrite in production welds shall be in accordance with AWS A4.2M:2006 (ISO 8249:2006MOD).

Weld Controlling - Deltaferrite



Source: Figure 1 of AWS A5.9/A5.9M:2006 ERRATA

Figure A.1—WRC-1992 Diagram for Stainless Steel Weld Metal

The WRC-1992 Diagram predicts ferrite in Ferrite Number (FN).

The WRC 1992 Diagram is preferred for “300” series stainless steels and for duplex stainless steels. It may not be applicable to compositions having greater than 1% Si

Weld Controlling – Delta ferrite

Ferrite in welds of austenitic stainless steels can be controlled by one or more of the following methods:

(a) Post weld solution annealing

(b) Use of weld filler with increased nickel content

(c) Increase of nickel equivalent by addition of approximately 1–3 vol.% nitrogen to shielding gas

(d) Selection of heats of materials with high nickel to chromium ratios, such as the European steel grade

1.4435 (see Table MM-2.1-1) with a restricted Cr(eq) to Ni(eq) ratio 3 as per BN2

Weld Controlling – Delta ferrite

The Basler norm 2 (BN2) describes the special material requirements of 1.4435 according to DIN 17440 with clearly narrowed analysis limits for the alloy components and defined ferrite content (ferrite).

Target delta ferrite is 3% at weld joint

Table MM-5.2.1.2-1 Predicted Ferrite Number (FN) Ranges for Various Austenitic Stainless Steel Product Forms and Welds

Product Form	Expected FN
Wrought product forms with sulfur levels less than 0.005%	0.5 to 4
Wrought product forms with a sulfur range of 0.005% to 0.017%	1.0 to 6
GMAW/GTAW using E316L [Note (1)]	4 to 12 [Note (2)]
SMAW using ER316L [Notes (3), (4)]	4 to 10 [Note (5)]
CF8M and CF3M castings	5 to 15

Weld Controlling – Delta Ferrite

Ferritoscope

Weld Controlling – Tungsten

Angle and profile of tungsten electrode is critical to maintain the weld bead width & profile

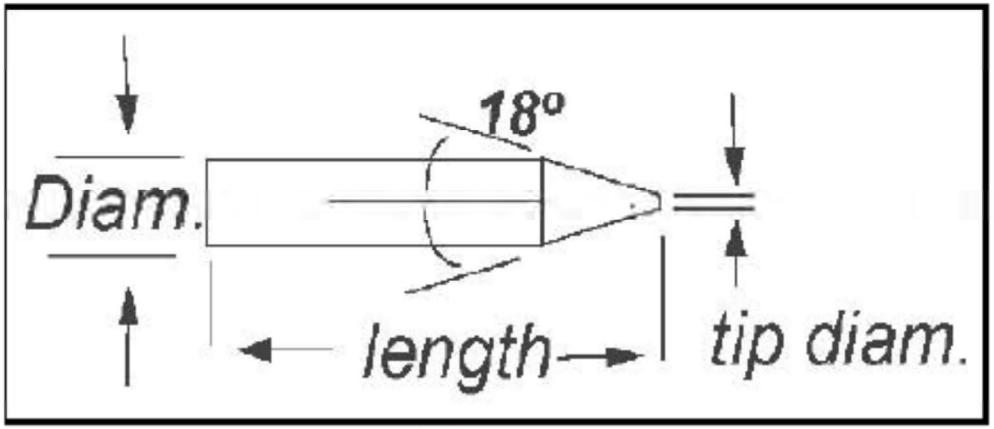


Fig. 11

Weld Controlling – Welder

- Welding Management System
- Certified Skilled Welder
- Welding Procedure
- Welder Qualification
- Weld Coupons before job

Welding Management System

Welding Management System

Uniqueness of Welding Operation

- Successful operation for obtaining defect-free welds ("sound") is largely determined by the welders' skill – called "Eye-Hand Motor- Coordination [EHMC]"
- The welder is a human being & hence subject to individual variability in traits & behaviors – eg, discipline, temperament, etc
- A large number of other engineering or technical factors need to be considered & planned in advance of the actual welding operations

Welding Management System

Other Unique features

- "Performance" of even the most "sound weld" during service can never be pre-determined but has to be assumed using corroborative inspection-reports, interpreting testing-results, judicious analysis, & good engineering judgment using experience gained from similar applications
- Un-predictability of "Distortion" is unique to welded structures, in that no other process introduces such critical un-certainty; causing serious delays, damages, or very costly rejections
- A wide range of "Welding Processes" are available & need to be carefully evaluated for the specific application; the most common ones for welding steel are: MMAW, TIG, MIG, SAW, Resistance, Stud, etc

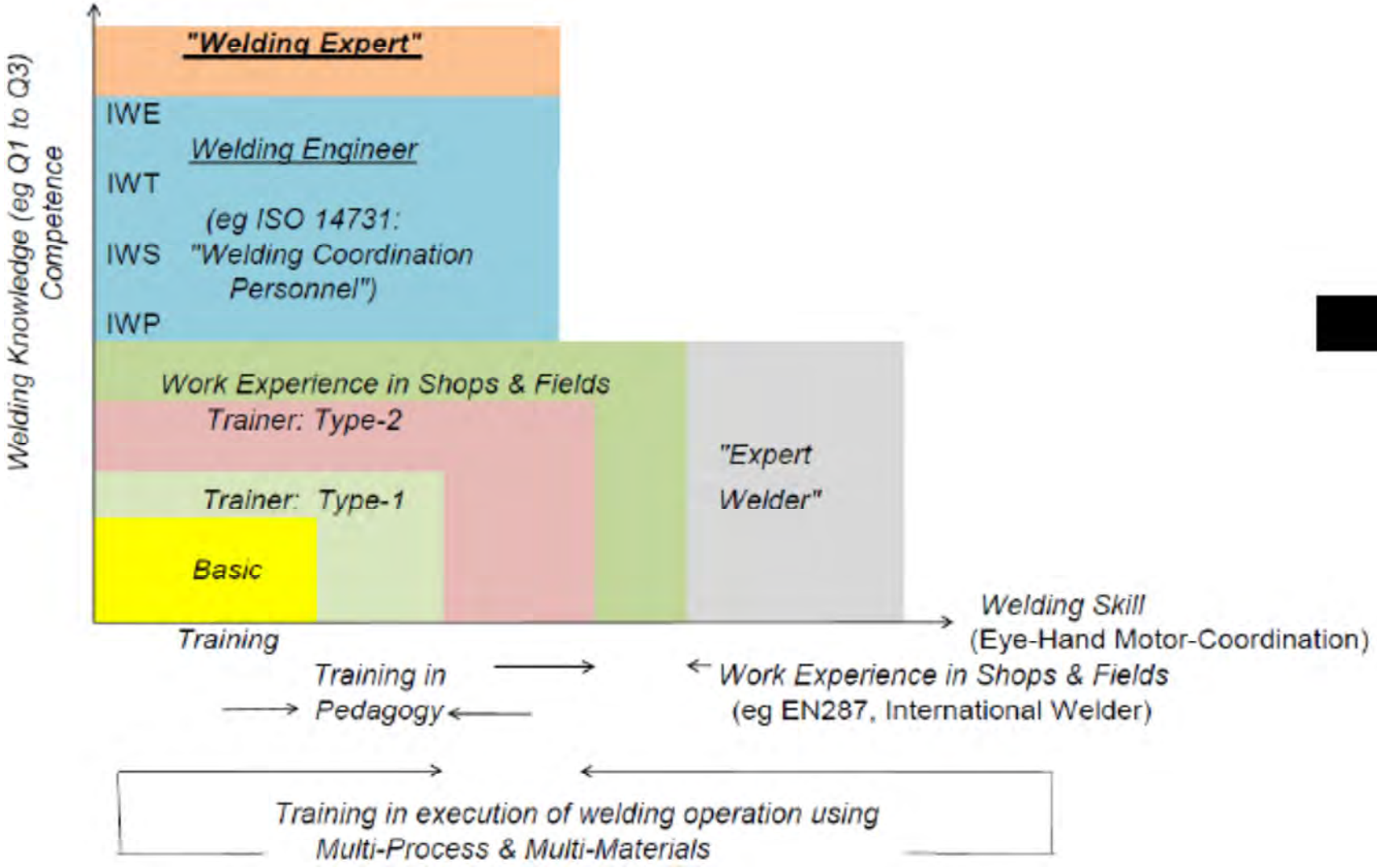
BIOZEEN

Quality of Weld Vs Performance of Weld

- These two terms are often mixed-up & needs clarification here
- Quality of the weld refers to its "sound-ness" ie "freedom from defects"
- "Performance" refers to how well the weldment discharges its designed function under the service conditions that it encounters during its life-time
- Therefore, while quality of welding is ***ESSENTIAL*** to contribute to its performance in service, it is ***NOT SUFFICIENT*** to ensure it!!

Welding Management System

Expert Welder Vs Welding Expert



Welding Management System

WPS, SWPS, WPQT

- The Welding Procedure Specification [WPS] is the heart of the Weld Management System [WMS]
- WPS is a document which un-ambiguously prescribes all necessary details which enable the execution of the welding operation
- SWPS is a standardized form of WPS which has been proved by a reputed 3rd party & hence is allowed to be used without qualification testing [WPQT]

Welding Management System

Moving Forward……..

- Welders are certified on the basis of their skill-competency for executing qualified welding procedures [WPS] using a standardized set of variables
- These qualified WPSs need to be be validated to suit the job
- The WPS is qualified thru mechanical testing to meet the structural strength & ductile-failure criteria called "design-performance", while the WPQ is tested for "soundness" or "quality"
- The Rules governing such qualifications are universally adopted by industry worldwide thru Codes & Standards (eg ASME BPV Sec IX & ISO 1561X

Welding Management System

Welding variables

- These are the specific inputs, values or factors which determine the outcome of the weld – either design-performance, soundness, or otherwise
- If all variables in the WPS are controlled during the execution of welding, the weldment can be expected to perform as designed

Welding Management System

Welding "variables" to be managed during the Opertion

- SUC: Set-Up Conditions – ie how the different parts are juxtaposed against each other at the joint ***prior to start*** of welding

- SWIP: Sequence of Welding & Inspection Plan – ie the detailed ***step-by-step actions*** to realize the weld – including inspection stages & post-weld operations

- RPC: Recommended Parameters Chart- ie what values of operating conditions of the Process to use ***during*** welding

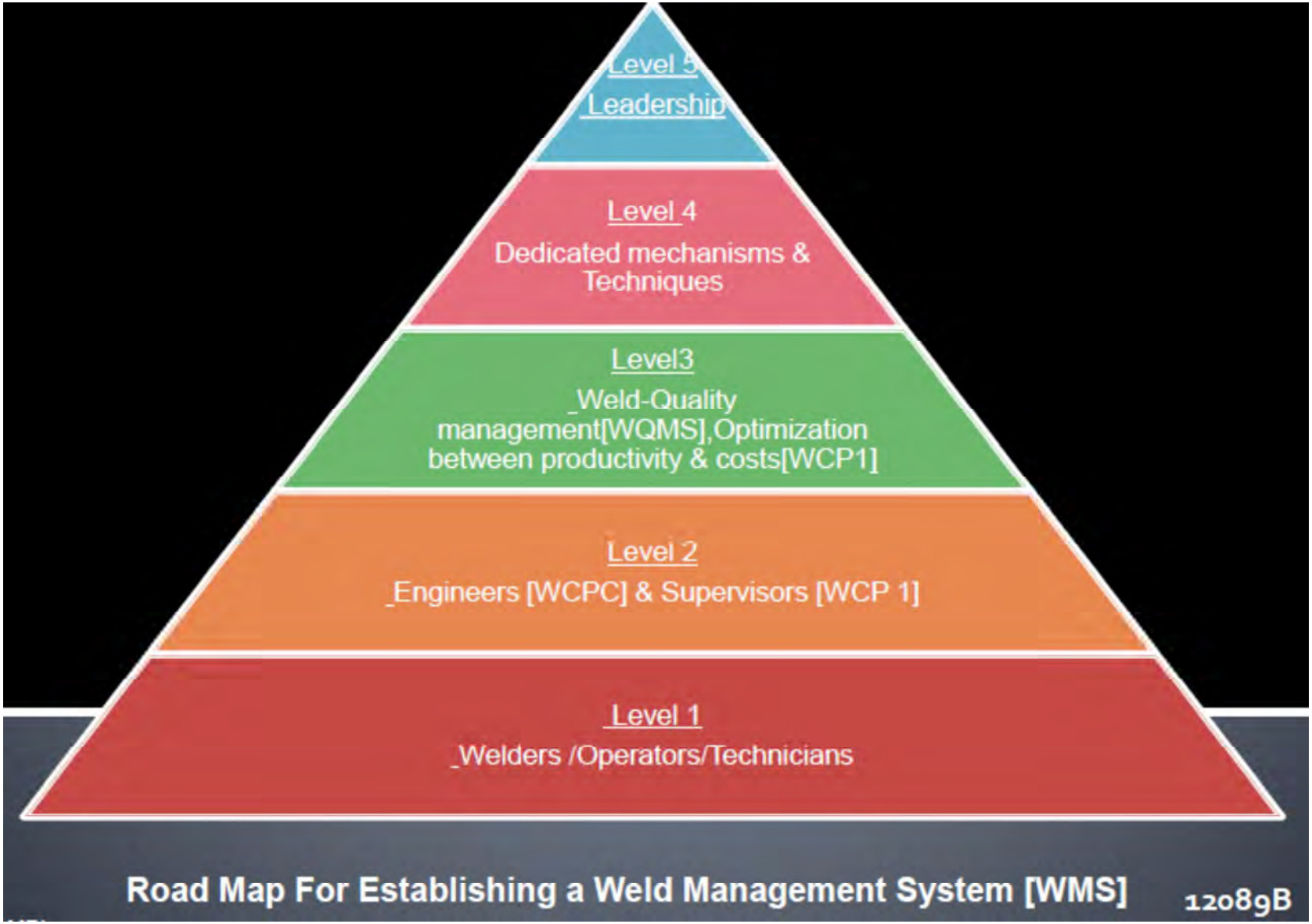
Welding Management System

Welding " Aspects" to be managed

- What about those factors which are to be planned ***in advance*** of the operation?
- Even if the skill-of-welding is to be eliminated thru a Robotic Arm, a lot of due diligence is required for selecting the right one for the application, & planning for procurement, installation & integration into manufacturing are required
- These need to be organized well in advance of the actual welding operation

Welding Management System

Road Map ……..



Welding Management System

Welding GAP Audit

The welding requirements of the Organization are closely scrutinized & compared wrt the mapping of its:

1. Current disposition of technology, practices, people, systems, etc

2. State of preparedness to meet its desirable future-state

The Top Management of the Organization supports this review by being closely associated with the Welding-Gap Audit

Welding Management System

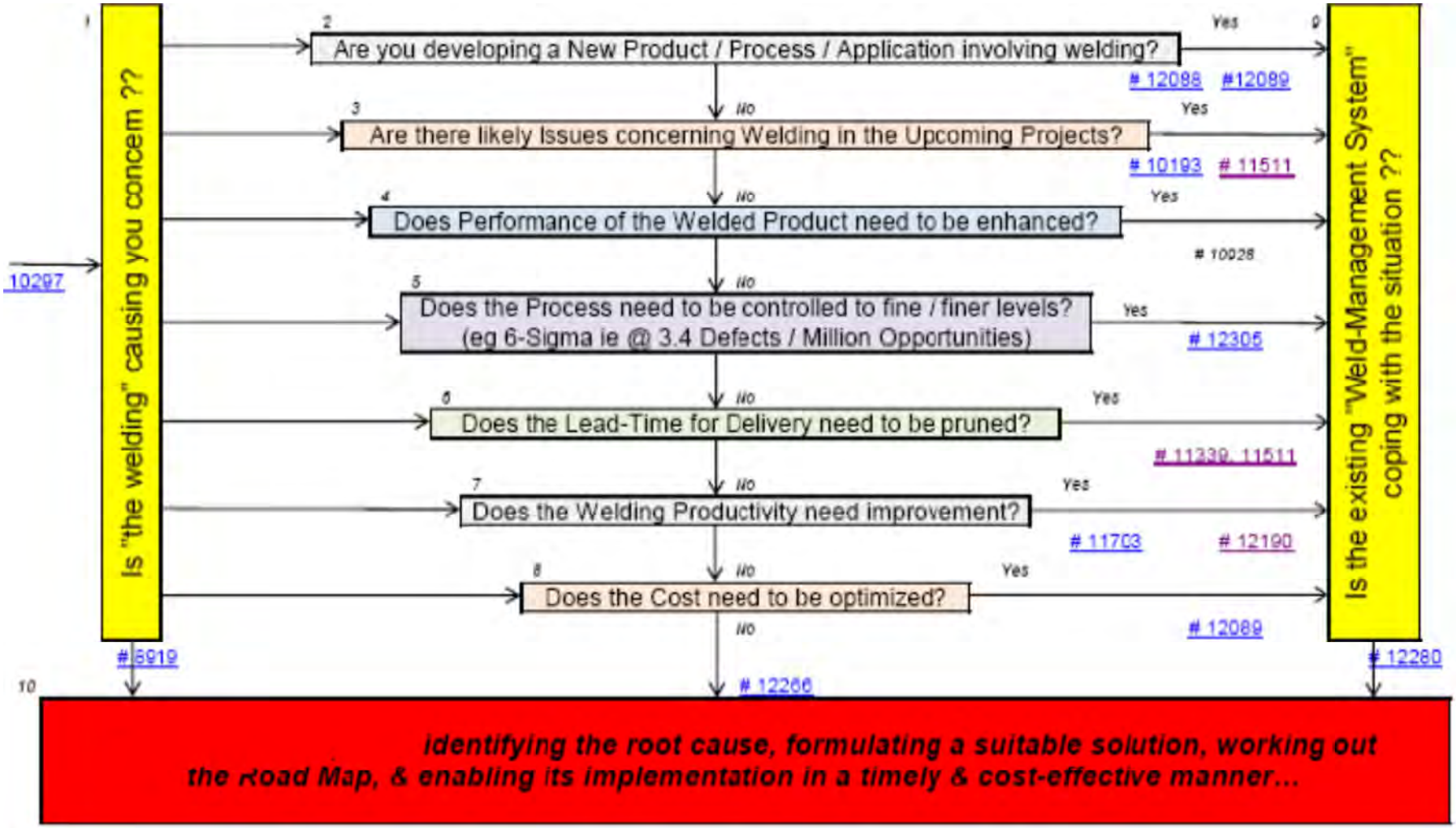
Welding GAP Audit

- The starting point is a self-assessment by the Top Management on the current dispositions & the aspirations of the Organization
- The Report with its Recommendations are used as the basis for charting out an Overall Road Map for establishing the WMS

Welding Management System

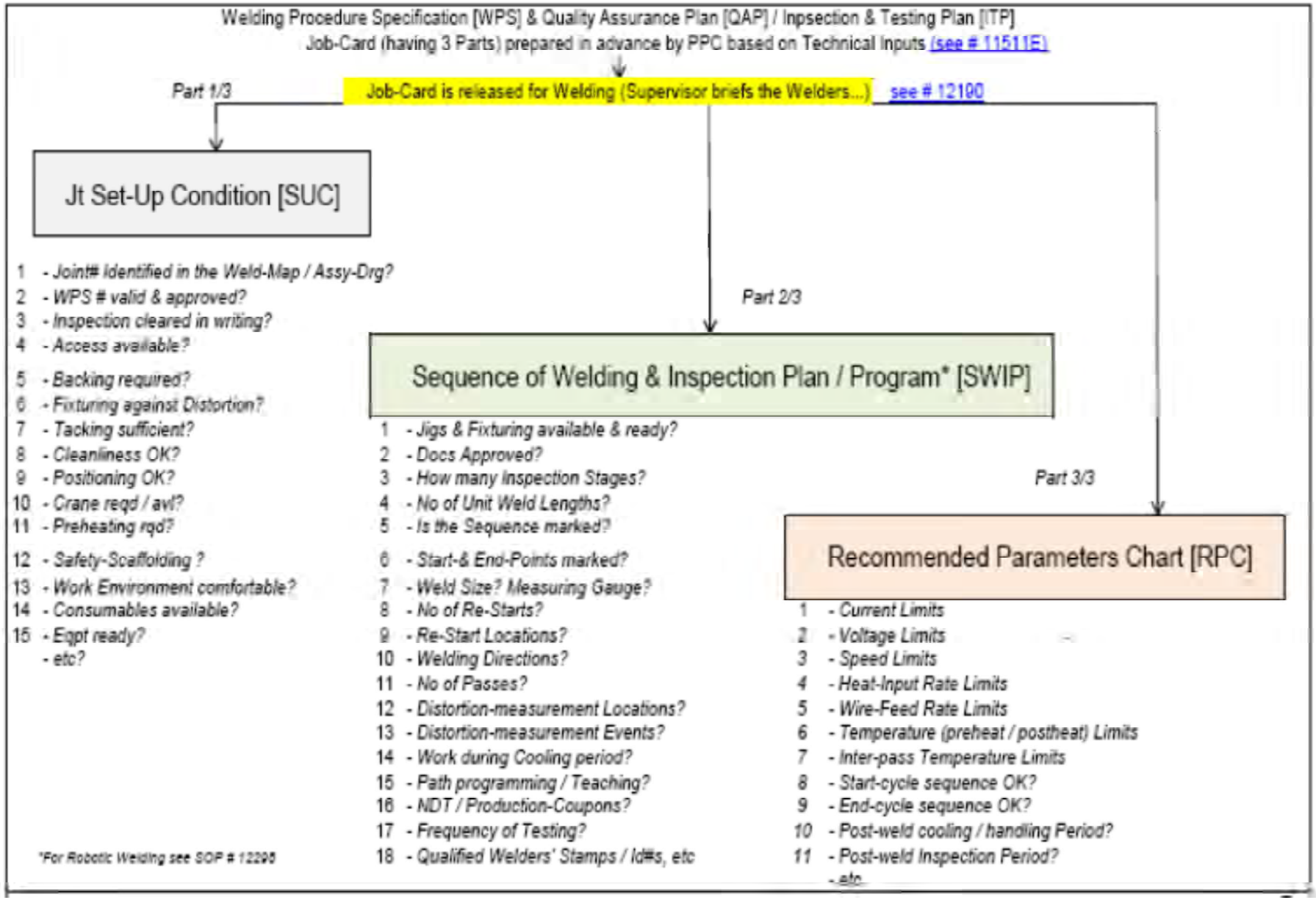
Welding GAP Audit

De-Burden your Welding !!



Welding Management System

Qualifications



Welding Management System

Overall Road Map

- This is a basic Project-Plan Document which divides the work into Phases, bifurcates the scopes & identifies the Key Change Agent
- The Project Manager & Project Leader are identified
- The Project Manager prepares the ORM

Welding Management System

Detailing Road Map

- This is jointly prepared by the Team Leader & the Project Manager
- In addition to detailing the above, it specifies the budgets, resources, schedules, re-structuring & re-organization, etc
- This detailed project plan is broken down into tasks ("Work Breakdown Structure")
- Broad phases for implementation are given in the next slide

Welding Management System

Stages of implementation of WMS

1. Establish the Top-Down "Organizational Framework" linking all the processes in the welding-functional chain for the product
2. Establish the Guidelines for Contract Review as related to Welding
3. Establish the Communication Sub-System, starting with Drgs released from the R&D / Design thru Mtls, SWIPs for Welders, etc, thru Insp & back to Mgmnt
4. Establish the traceability-routes for materials, consumables, processes, etc
5. Establish the WPS, WPAR, WPQ, Sub-Systems; qualify the welders to meet the demand of skill-competency
6. Deploy the skills according to the MATRIX
7. Verify the performance from Service & feedback from Customer / User
8. Document all the above processes; review & improve

Welding Management System

Practising WMS

- After establishing the above processes, run thru the system for several cycles / iterations for all critical / identified jobs over a pre-determined period of time
- Track the history, experiences, feedbacks, etc, & update the documentation
- Improve & scale up in a calibrated manner to cover all the job-orders (or pre-determined %, as appropriate for the level of control – ie ISO 3834-2, 3, OR 4)
- When ready, apply for Certificate to Manufacturer's Certification Body for Audit to ISO 3834 (or as appropriate)

Welding Management System

Concluding WMS

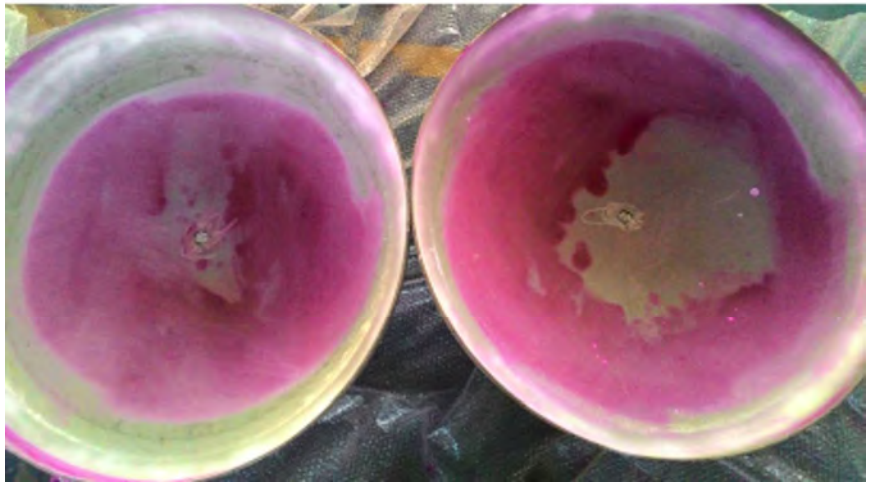
- The WMS can be implemented in any Organization where welding plays a critical role
- The Organization can implement it systematically well in advance of actually executing major project-orders
- The Welding-Gap Audit is the basic 1st step in implementation of WMS
- Road Maps for successfully establishing the WMS can be formulated to suit the Organization's needs

Welding Controlling

Weld Controlling – NDT

- **Radiography Inspection**

- **Dye Penetrant Test**

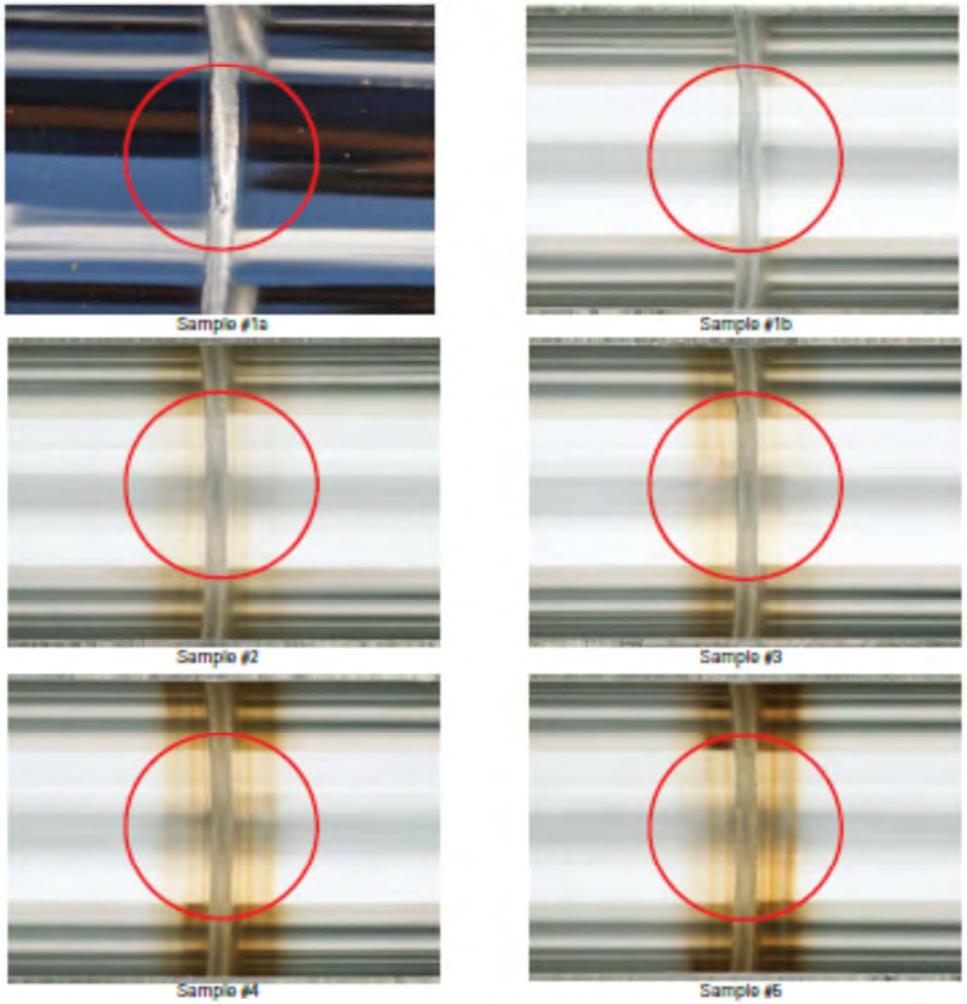


- **Borescope**

Weld Controlling – NDT

Weld Controlling – NDT

Fig. MJ-8.4-2 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Electropolished UNS S31603 Tubing (1



The weld beads shown in the above photographs are the weld beads on the I.D. of the tubing. The area for comparison in each photograph is the area inside the red circle. The weld bead shall have no discoloration. Weld heat-affected zones on electropolished UNS S31603 tubing with discoloration levels no worse than Samples #1 through #4 in the as-welded condition are acceptable. Heat-affected zone discoloration levels more severe than that shown in Sample #4 are unacceptable. Sample #5 shows unacceptable weld and heat-affected zone discoloration levels for comparison. The user is cautioned that the colors observed during direct visual examination or borescope examination will be different viewing directly down (90 deg) at the surface compared with viewing at a lower angle along the edges.

GENERAL NOTE: The user is cautioned that electronic versions or photocopies of these acceptance criteria shall not be used for evaluation of sample or production welds since subtle differences in color can influence weld acceptability. Nonmandatory Appendix M explains the technique by which these acceptance criteria were determined.

This figure is also available as a stand-alone document from ASME as ASME BPE-EP.

Weld Controlling – Documentation

Equipment Name:
Equipment Model No:

CHECKLIST FOR MANUFACTURING DOCUMENTATION OF BIOPROCESS EQUIPMENTS

-.-	DOCUMENT TYPE	STATUS
VESSEL (shell, lid and internal accessories) >> DOCUMENTS FROM 3rd PARTY		
1	MOC Test Certificate for vessel components (contact part and non contact part)	
2	Dimensional report	
	Fit up reports	
	Nozzle set up reports	
3	Welding procedure Qual	
	Welders Qualification certificate for welders no:	
	Weld drawing	
	Weld log sheet	
	Quality certificate for TIG electrode	
	Quality certificate for filler wire	
	Quality certificate for Argon gas purity	
	Radiography Test Certificate only for seam welds	
	Radiography films	
4	Dye Penetrant test report for nozzle welds	
	Dye Penetrant test report for seam welds	
5	Vessel Hydro test (procedure + report)-from BZ	
	Jacket Hydro test (procedure + report)-from supplier	
	Vessel Drainability (procedure + report)	
6	Ra Report for vessel internal (external optional)- final from BZ	
PIPES (purchased and used as it is)		
In contact with product	**Not in contact with product**	
1	MOC Test Certificate Ra Test Certificate	MOC Test Certificate
VALVES		
In contact with product	**Not in contact with product**	
1	MOC Test Certificate for body Electropolishing certificate MOC Test certificate for diaphragm (FDA / USP)	MOC Test Certificate for body
MACHINED CONNECTORS / BBL COMPONENTS (steel purchased and transformed at BZ)		
In contact with product	**Not in contact with product**	
1	MOC Test Certificate for SS Electropolishing certificate Nesting drawing Ra Graphs	MOC Test Certificate for SS
EQUIPMENT		
1	Weld map Weld log sheet Weld print outs Welders Qualification certificate Welding Qualification sample Quality certificate for filler wire Quality certificate for Argon gas purity	
2	Passivation report	
3	MOC Test certificate for piping O ring / gaskets + vessel lid	
In contact with product	**Not in contact with product**	
4	Boroscopy images for process lines: 100% for manual welds 50% for orbital welds	Boroscopy images for utility lines: Overall 10%

SEPARATE FILE: TESTING INSTRUMENTS CERTIFICATES (from supplier + BZ)

1	Calibration certificate for Ra meter standard piece	
	Calibration Certificate for Gauges used for PHT	
	Calibration Certificate for measuring instruments (tape / caliper / level)	

Weld Controlling – Documentation

Filler Rod Certificate

ISO 9001:2015 CERTIFIED

No. WL/VW/2018-19/7340

INSPECTION /MILL/MATERIAL/QUALITY /EN 10204/3.1 CERTIFICATE

PRODUCT INFORMATION			
CUSTOMER	: BENAKA INDUSTRIAL PRODUCT	GRADE :	ER-316L/1.4430
INVOICE NO.	: 4569/2018-2019	HEAT NO	: V13129
PRODUCT FORM	: STAINLESS STEEL WELDING WIRE		
DIMENSION	: 2.40mm Tol :- ±0.05mm		
IDENTIFICATION	: BOX NO. : HH 01-8	QUANTITY	: 200 KGS
CONDITION	: BRIGHT DRAWN & CUT LENGTH (1000 MM).		

CHEMICAL COMPOSITION		C%	Si%	Mn %	P%	S%	Cr %	Ni %	Cu%	Mo %	N%	Nb%	Ti%	---
ELEMENTS														
SPECIFIED	MIN			1.00			18.00	11.00		2.50				
	MAX	0.03	0.65	2.50	0.03	0.02	20.00	14.00	0.50	3.00				
RESULTS		0.019	0.42	1.70	0.026	0.008	18.50	11.16	0.26	2.57	-----	-----	-----	---

MECHANICAL PROPERTIES OF WELD METAL(All Weld)

RESULTS	UTS N/mm²	YS (0.2%) N/mm²	R.A. %	ELONGATION %	HARDNESS	
	577	430	---	40.00	--	

Weld Controlling – Documentation

Argon Gas Certificate

Sl.No.	BGL Cylinder No.	Hydrogen
1	BGL13680	2.07 %
2	BGL1530	2.08 %
3	BGL1607	2.07 %
4	BGL12259	2.06 %
5	BGL20746	2.07 %
6	BGL22081	2.07 %
7	BGL2371	2.06 %
8	BGL24347	2.06 %
9	BGL24380	2.06 %
10	BGL24393	2.07 %

Impurities:-
BGL1607 – CH4<0.10 PPM

20 Apr 2019

Q.C. VERIFIED BIOZEEN

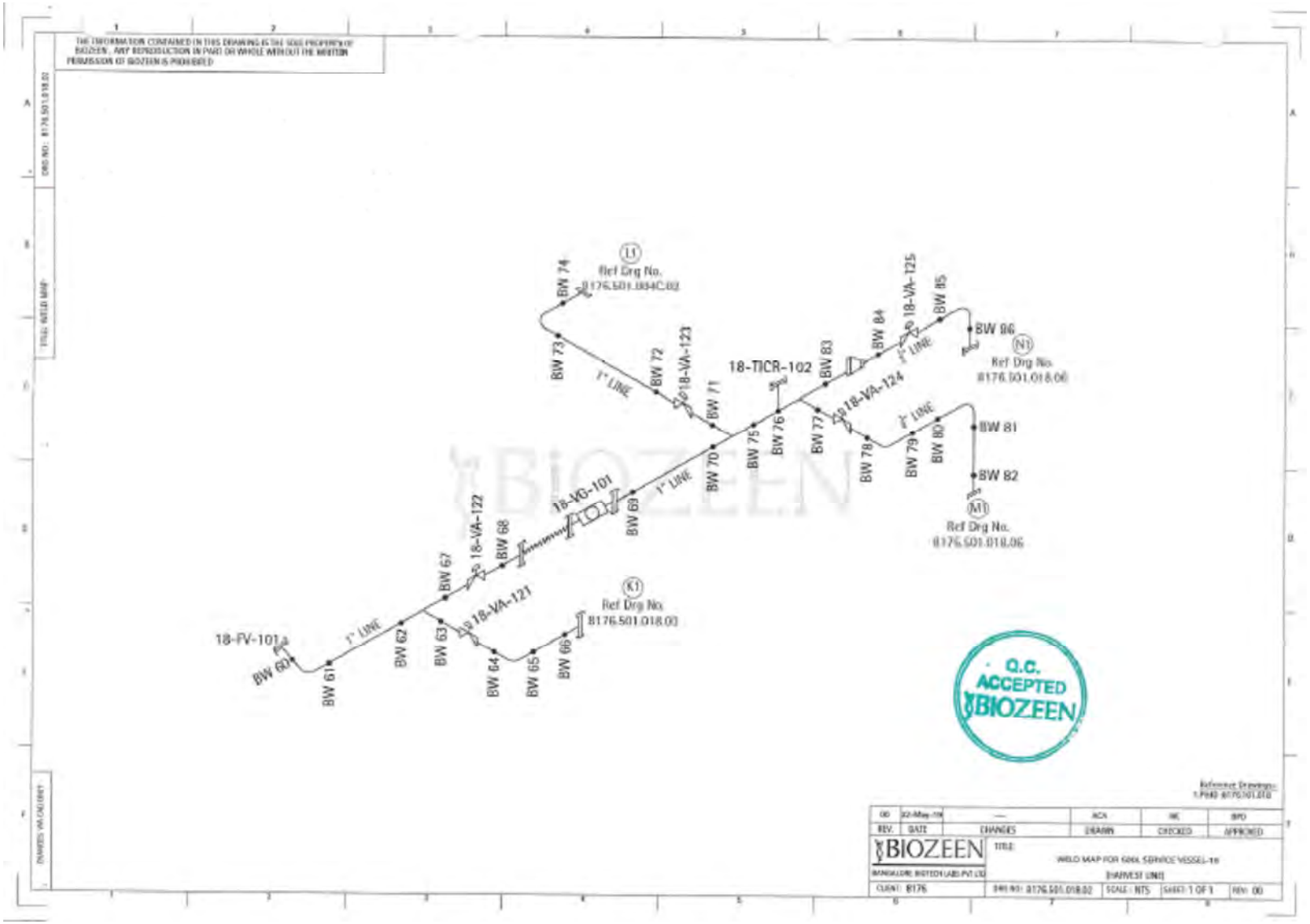
The Concentration of Impurities in this mixture AHM 98:2 are O2<1.0 ppm. H20<1.0 ppm and dew point –76°C. The Concentration of Argon on AHM is 98.0 %.
Remarks: Raw Material Purity – Hydrogen (99.999 %) & Argon (99.9995 %).
Impurities of raw materials are O2<2.0 ppm, H2O<2.0 ppm and THC<0.5 ppm.

Traceability Certification :

1. The Product is prepared by using Weight/Pressure Gauge of Accuracy Traceable to National Standards Through Regional Reference Standard Laboratory (Weights and Measures) Govt. of India.
2. The Product is certified using Reference Standard Traceable to NIST/NPL.
3. Process Traceability complying with ISO 9001:2015 Certified System.

Weld Controlling – Documentation

Weld Isometric Diagram



Weld Controlling – Documentation

Weld Log

FORMAT NO:BBL/ENGG-QC/R/WEL.001/R02

BIOZEEN

WELD LOG - Harvest Line

Project No. : 8176	**Customer :** SERUM INSTITUTE OF INDIA PVT. LTD	**Equipment/System:** 500L SERVICE VESSEL - 18
Weld Map No. : 8176-501-018-01 to 05	**Welding Gas:** AHM	**Welding Procedure:** 005, 011
P & ID No. : 8176-101-018	**Shielding Gas:** AHM	

Weld no.	Welding Procedure: Manual	Welding Procedure: Orbital	Description	Heat no/Lot no:	Welding: Date	Welding: Welder ID/Sign	Inspection: Boroscope	Inspection: Image captured	Checked by Welding Inspector & Date	Accepted: Yes	Accepted: No	Corrective Action	Remarks
BW 60	–	✓	½" TC x 1" PS 1" PS 316L elbow	BZ-VI-825/18-19 469A	29 APR 2019	W9	✓	–	29 APR 2019	✓	–	–	–
BW 61	–	✓	1" PS 316L elbow 1" PS 316L pipe	469A 425F	29 APR 2019	W9	✓	–	29 APR 2019	✓	–	–	–
BW 62	–	✓	1" PS 316L pipe Unequal Tee 1" x ½"	425F 848700/Y8H8	29 APR 2019	W9	✓	–	29 APR 2019	✓	–	–	–
BW 63	✓	–	Unequal Tee 1" x ½" Diaphragm valve ½" PS	848700/Y8H8 748146 A TK	30 APR 2019	W7	✓	✓	30 APR 2019	✓	–	–	–
BW 64	✓	–	Diaphragm valve ½" PS ½" SS 316L Elbow	748146 A TK 208575	30 APR 2019	W7	✓	✓	30 APR 2019	✓	–	–	–
BW 65	–	✓	½" SS 316L Elbow ½" SS 316L Pipe	208575 547422	30 APR 2019	W17	✓	–	30 APR 2019	✓	–	–	–
BW 66	–	✓	½" SS 316L Pipe ½" TC x ½" PS	547422 BZ-VI-827/18-19	30 APR 2019	W17	✓	–	30 APR 2019	✓	–	–	–
BW 67	✓	–	Unequal Tee 1" x ½" Diaphragm valve 1" PS	848700/Y8H8 741035 ALR	30 APR 2019	W7	✓	✓	30 APR 2019	✓	–	–	–
BW 68	–	✓	Diaphragm valve 1" PS 1½" TC x 1" PS	741035 ALR BZ-VI-825/18-19	29 APR 2019	W9	✓	–	29 APR 2019	✓	–	–	–
BW 69	–	✓	1½" TC x 1" PS 1" SS 316L Pipe	BZ-VI-825/18-19 425F	29 APR 2019	W9	✓	–	29 APR 2019	✓	–	–	–

8176.018 500L SERVICE VESSEL - 18

Weld Controlling – Documentation

Traceability and Identification

Weld Controlling – Documentation

Weld Printout

001 0.5 INC
Pg 01
Number 19

		U (V)	I (A)	V rot (mm/min)	V wir ( )
	5s	0.4	0.2		0
	10s	0.3	0.3		0
	15s	0.4	0.2		0
S01	1°	10.9	49.9	21	0
		10.2	17.1		
	10°	10.8	49.9	90	0
		10.2	17.1		
	20°	10.9	49.9	90	0
		10.5	17.1		
	30°	11.0	49.9	90	0
	440°	9.6	22.3	90	0
		10.3	10.6		
	451°	10.0	18.9	90	0
		10.9	9.2		
	460°	10.8	15.6	90	0
		11.4	8.5		
	470°	11.3	13.6	90	0
		12.5	7.5		
	480°	11.8	10.3	90	0
		12.9	6.6		
	491°	13.1	7.4	90	0
		13.9	5.7		

>>>>>>>>>>>>>>> ! OK ! <<<<<<<<<<<<<<<
Cycle start: Sat 09 Mar 2019 00:24:17
Cycle time : 00:01:18 N = 495

>>>>>>>>>> ! Weld comments ! <<<<<<<<<<

BIOZEEN_W16.8176.010.700L.AV-10
BW-350
09 Mar 2019

Weld Controlling – Documentation

Welder Qualificatior

Designation **Welder Qualification** **BS EN ISO 9606-1 141 PBW FM5 S t1.65 H-L045 ss gb**

WPS-Reference: 004 Rev.01 Examining body : Lloyds Register Verification Limited

Welder's Name: **Mr. Mansoor Pasha**
Identification: **W12**
Method of Identification: Company Identification
Date and place of birth: 01-01-1985 & Near Bangalore, Karnataka, India
Employer: M/S. Bangalore Biotech Labs Pvt.Ltd
Code / Testing standard: BS EN ISO 9606-1 : 2017
Remark: None
Job knowledge: Acceptable

	Weld test details	Range of approval
Welding process(es)	TIG(141)	TIG(141)
Transfer Mode	NA	NA
Product type (plate or pipe)	T	T
Type of weld	BW	BW
Joint type	P BW ss gb	P BW ssmb , P BW bs, P BW ssgb
Parent Material group(s)/subgroups	ISO CR 15608 Group 8.1	ISO CR 15608 Group 8.1
Filler material group (s)	FM5	FM5
Filler material (Designation)	Solid (S)	Solid (S) , Metal Cored (M)
Shielding gas	Argon: Hydrogen Mixture(or equivalents) EN ISO 14175 : AHM	Argon: Hydrogen Mixture (or equivalents) EN ISO 14175: AHM.
Auxiliaries (e.g. backing gas)	Argon: Hydrogen Mixture(or equivalents) EN ISO 14175 : AHM	Argon: Hydrogen Mixture (or equivalents) EN ISO 14175: AHM.
Type of current and polarity	DCEN	DCEN
Material thickness (mm)	1.65	1.65 to 3.3.
Deposited thickness (mm)	NA	NA
Outside Pipe diameter (mm)	OD 50.8	OD ≥25.4mm.
Welding position(s)	H-L045	PA , PC , PE , PF
Weld details Multi-layer/single layer	(ss , gb) sl	(ss , gb) , (ss , mb) , bs sl

Additional information: available in WPS 004

Type of qualification tests	Performed and accepted	Not tested
Visual testing	☒	☐
Radiographic testing	☒	☐
Macroscopic examination	☐	☒
Fracture test	☐	☒

Name of the Examiner : D. SUNDARESAN
Place : BANGALORE
Date of issue : 26/04/2018
Signature of Examiner :

Lloyd's Register Verification Limited
DURAISAMY SUNDARESAN
☑ WITNESSED ☐ REVIEWED

Weld Controlling – Documentation

Welder Qualification

BIOZEEN

QW-484A - WELDER PERFORMANCE QUALIFICATION (WPQ)
(See QW-301, Section IX, ASME Boiler and Pressure Vessel Code)

Welder's name: Mr. Mansoor Pasha **Identification No. : W 12**

Test Description
Identification of WPS followed: **011 Rev 00 DT 04.01.2017** ☐✓Test Coupon ☐ Production Weld
Specification and type/grade of Base Metal : Thickness : 1.65 mm
ASME SECII PART A.ED.2015 ASTM A 270/SA 213/SA213M
TYPE 316L

Testing Condition and Qualification limits

Welding variables (QW-350)	**Actual values**	**Range Qualified**
Welding Process	GTAW	GTAW
Type	Manual	Manual
Backing	Without Backing	With or Without Backing
Plate or Tube	Pipe (OD12.7mm)	Plate & Pipe (OD ≥ 12.7mm)
Base metal P- Number to P- Number	P8 to P8	P1 thro P15F, P34, P41 Thro P49
Filler metal or Electrode specification	None	None
Filler metal or Electrode Classification	None	None
Filler Metal F Numbers	None	None
Consumable Inserts (GTAW or PAW)	None	None
Filler type (solid/metal or flux cored/powder)	None	None
Deposit thickness for each process	1.65 mm	1.65 mm
Position(s)	6G	All
Vertical Progression (uphill or downhill)	Downhill	Downhill
Type of fuel gas (OFW)	NA	NA
Inert gas backing (GTAW, PAW, GMAW)	AHM (Argon 98% & Hydrogen 2%)	AHM (Argon 98% & Hydrogen 2%)
GTAW current type	DCEN	DCEN

Weld Controlling – Documentation

Weld Coupon

References

- ASME BPE 2016
- https://www.nickelinstitute.org/media/1702/highperformancestainlesssteels_11021_.pdf
- Guidelines for the welded fabrication of nickel-containing stainless steels for corrosion resistant services Nickel Development Institute o Reference Book, Series N 11 007
- DESIGN GUIDELINES FOR THE SELECTION AND USE OF STAINLESS STEEL Nickel Development Institute o Reference Book, Series N 9014
- ASME Section VIII (Rules for Construction of Pressure Vessels)
- ASME Section IX (Welding, Brazing & Fusing)
- ASME Section II (Materials)

Thank You !