



Schedule

- 8:30 am – Arrival and Registration
- 9:00 am – Introductions
- 9: 15 am – Mosaics & Debrief
- 10:00 am – SLCC's Biomanufacturing Program
- 10:10 am – Leadership & Biomanufacturing
- 11:00 am – MarbleWorks & Debrief
- 12:00 pm – Box Lunch & Campus Tours

2



Introductions

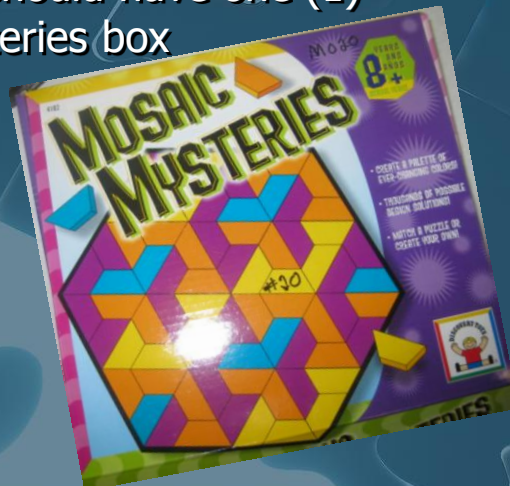
- **Marian Howe-Taylor**
 - Community Outreach and MESA/STEP Initiatives
- **Vivian Ngan-Winward, Kasey Schuster**
 - SLCC Biomanufacturing Program
- **Dr. Clifton Sanders**
 - Dean
- **Dr. Marlin Clark**
 - Dean of Students
- **Jeffrey Ojeda**
 - Mathematics Engineering Science Achievement (MESA), Utah State Office of Education

3



Mosaics Activity

- Every table should have one (1) Mosaic Mysteries box



4



Mosaics Activity

1. Purpose:

1. To assemble the mosaic design.

2. Scope:

1. This procedure should be followed to assemble the mosaic design using the Mosaic Mysteries kit.

3. Responsibilities:

1. Workers using this procedure must be adequately trained to perform this procedure.
2. Workers using this procedure are responsible for following the facility's safety procedures.
3. Workers using this procedure are responsible for following proper documentation policies.

4. References:

1. SOP-1111 *Facility Rules and Regulations*
2. SOP-2222 *Proper Documentation Procedures*
3. BR-1234 *Mosaic Design Assembly*

5. Definitions:

- "Mosaic piece" means any of the colored trapezoidal plastic pieces in the Mosaic Mysteries kit.

6. Precautions:

- Take care not to lose any mosaic pieces from the kit.
- Assembly should be performed on a level work surface.



Mosaic Activity

- Record the lot number for each one of the materials used.
- Complete the batch record as directed.
- Before beginning, make sure your work area is clean. If needed, wipe area with damp paper towel and discard towel.
- Take inventory of the materials in your Mosaic Mysteries kit and complete the material inventory in *Assembly* section of the batch record.



Mosaic Activity

- Using the mosaic pattern on your sheet as a guide and assemble the mosaic design by placing the mosaic pieces in the display tray.
- When placing the mosaic pieces, start from the outside edge and work toward the center of the design.
- When assembly is complete, report to your supervisor and obtain from him/her the *Batch ID* number.
- Complete the remaining parts of the *Assembly* section in the batch record. Your supervisor should complete the *Work Review* section of the batch record.

7



Mosaic Activity

- Now that we've gone through the first 6 steps, it's time to complete the activity on your SOPs!
- You will have 10 minutes to complete this activity and then we'll discuss.

8



Mosaic Results

- What did you end up with?



9



Mosaics Debrief

- Why did some groups get a picture different from the planned design?
- In the Biomanufacturing industry,
 - Product Quality;
 - Safety;
 - Effectiveness;
 - Customer Satisfaction;
- Each of these depend on using the correct instructions and materials to make the product, whether it is drugs, medical devices, dietary supplements or other biomanufactured product.

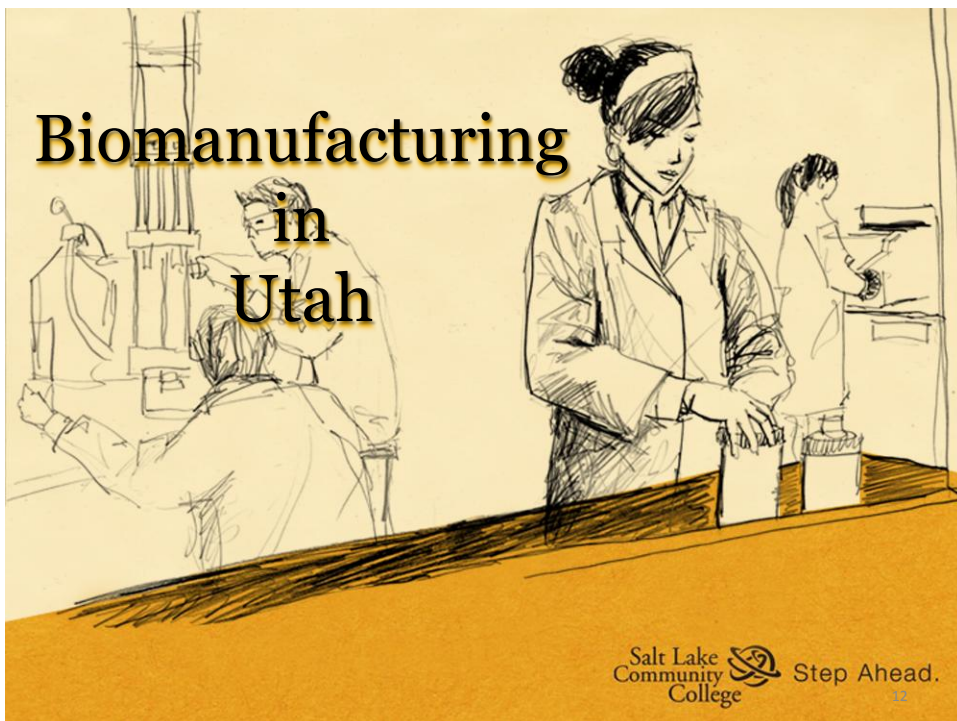
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Biomanufacturing at SLCC

- So let's learn more about the
- BIOMANUFACTURING INDUSTRY

11



WHAT IS BIOMANUFACTURING?

The making of useful products:

- Using technology based on biology (e.g. cellular and/or biomolecular processes)
- or
- To solve a biology-based problem

13

FIRST BIOMANUFACTURED PRODUCTS



14

CURRENT PRODUCTS



15

TOP 3 INDUSTRY SECTORS

1. Natural products & dietary supplements
2. Medical devices
3. Pharmaceuticals

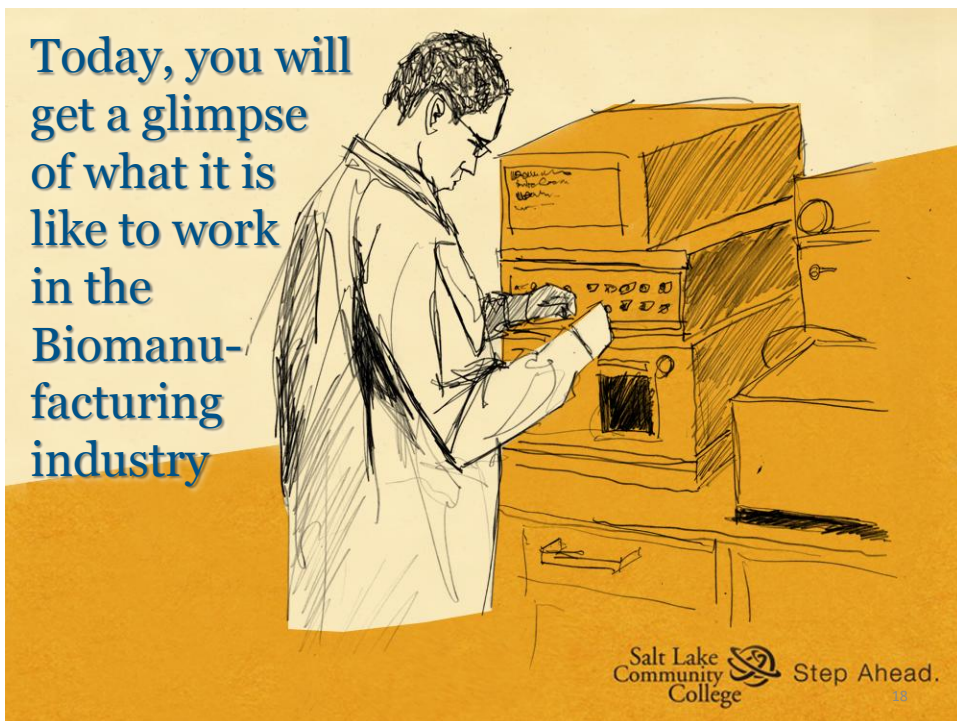
* High growth sectors in Utah

16

AVAILABLE CAREER PATHS

- Research & Development
- Process Development / Product Transfer
- Production
- Quality Assurance
- Marketing

17





Leadership in Biomanufacturing

- Perfect sense?
- Ready to start the job?
- Biomanufacturing is
 - technical,
 - hands-on, and
 - requires important leadership skills to be successful.



19



Leadership in Biomanufacturing

But, before we start,
we should set the tone with a cool tune.

Let's talk about....

- How to be successful today and also in your future;
- Especially if you decide to work in the biomanufacturing industry.



20

Biomanufacturing Career Paths

- I've got a feeling....
- I want to find the cure for....



MAKE-A-WISH.

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Research & Development
 Process Development / Product Transfer
 Production
 Quality Assurance
 Marketing

21

Not an Isolated Process

- Research & Development
- Process Development / Product Transfer
- Production
- Quality Assurance
- Marketing



22



Leadership & You

- Leadership Revisited
 - Leadership is the skill of influencing others to *work enthusiastically* towards a goal identified as being **for the common good.**

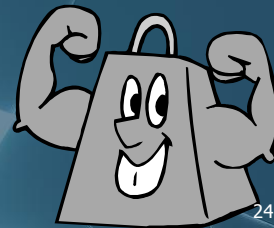


23
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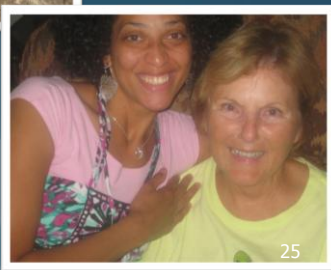
Leadership – Hard Skills

- "Hard Skills" Defined
 - The abilities you have that allow you to get the job done.
 - Ability to follow directions;
 - Attention to detail;
 - Consistency;
 - Dedication



Hard Skills & Lessons Learned





25

Biomanufacturing Hard Skills

• Ability to Follow Directions • Conflict Management/Resolution Skills • Ability to Take Initiative • Consistency • Dedication • Dependability • Drive/Determination • Endurance • Flexibility/Adaptability • Honesty • Initiation • Integrity • Intelligence	• Leadership • Maturity • Mechanical ability • Motivation (to do the work) • Multi-tasking Ability • Persistence • Physical Energy • Preciseness • Problem Solving Ability • Organizational skills • Responsibility • Self-Control • Tenacity • Work ethic
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26

<http://cse.edc.org/products/biomfgskills/PDFs/2traitsCharacteristics.pdf>



Leadership – Soft Skills

- “Soft Skills” Defined
- The way you use your leadership to influence people to get the job done.
 - Approachability
 - Creativity
 - Curiosity/Ability to Question
 - Diversity Understanding
 - Friendliness
- It’s the ability to make people “fall in love” with your leadership style.



27



28

Biomanufacturing Soft Skills

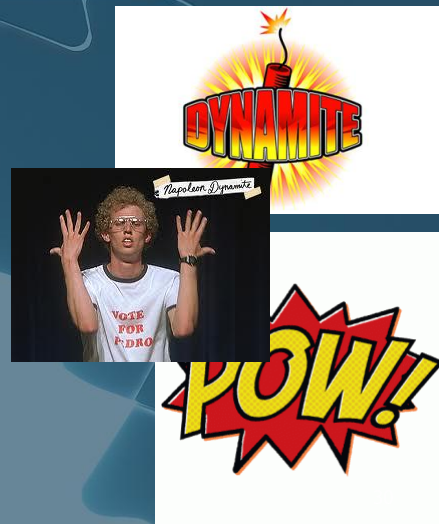
- | | |
|---|---|
| <ul style="list-style-type: none"> • Ability to Maintain Perspective • Ability to be Self Critical • Ability to Take Criticism • Ability to Handle Stress • Approachability • Assertiveness • Common Sense • Creativity • Curiosity/Ability to Question • Diversity Understanding • Friendliness • Generosity | <ul style="list-style-type: none"> • Resiliency • Resourcefulness • Respectfulness • Respect for Authority • Self-Confidence • Sense of Humor • Sense of Ownership • Tactfulness • Team Player • Willingness to Learn |
|---|---|

29

<http://cse.edc.org/products/biomfgskills/PDFs/2traitsCharacteristics.pdf>

Leadership Hard Skills, Soft Skills, or ???

- 100% Hard Skills
- 100% Soft Skills
- Different Approach?





31



MarbleWorks Activity Peter's Pills

- Peter is the owner of Peter's Pills.
- The company manufactures pills for treatment of assorted conditions such as having bad hair days and wearing mismatched shoes.
- Peter is interested in improving his manufacturing process & his profitability.

32



MarbleWorks Activity

- As his design manufacturing team, your job is to develop a new production line for him.
- Do this by constructing a new production line using the marble maze kit, and then testing the line by producing batches, each one consisting of 6 pills (marble runs).
- Analyze the results of these batches to determine the profitability of your production line.

33



MarbleWorks Activity

- See the instructions on the "Controlling Variation" page for details on how to do this.
- Your goal is make 8 batches of 6 pills each, and see if you can consistently turn a high profit.

34



Here is the cost schedule related to testing the new production line.

Income

Action	Income
Income per pill successfully made (marble completes the maze)	\$100/pill

Expenses

Action	Expense
Cost to develop & build maze	\$1500 / factory
Minor design change (tighten or adjust a piece)	\$50 / piece
Redesign (move a piece to a different location)	\$100 / piece

35



MarbleWorks Debrief & Application

- There are many costs related to manufacturing that impact net profit
 - Set-up costs for equipment,
 - Process development costs to optimize the manufacturing process, and
 - Costs for waste related to a defective product that cannot be sold.
- Product quality, safety, and effectiveness cannot be sacrificed for higher profit.

36



MarbleWorks Debrief

- FDA regulations require that *whenever changes (i.e. tweaks or redesigns) are made to the process, the manufacturer has to perform new validation testing to prove that **the process still gives the expected product***, so this may be an unexpected cost that is incurred.
- If the right forethought is put into product and process development up front, there will be less changes and thus higher net profit.

37



Leadership Lesson for the Day

- "Cultivate Determination"
- "Effort only fully releases its reward after a person refuses to quit."
Napoleon Hill
- To develop persistence over the long haul, you have to cultivate inward determination on a continual basis.

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Leadership Lesson for the Day

- "Cultivate Determination"
- Learn to become a determined individual.
- The only difference between a little shot and a big shot is that the big shot kept shooting.

© John C. Maxwell's "The Maxwell Daily Reader" – December 10th 39

Peter's Pills Production Plant

Peter is the owner of Peter's Pills. The company manufactures pills for treatment of assorted conditions such as bad hair days and mismatched shoes.

Peter is interested in improving his manufacturing process & his profitability.

As his design manufacturing team, your job is to develop a new production line for him. Do this by constructing a new production line using the marble maze kit, and then testing the line by producing batches, each one consisting of 10 pills (marble runs). Analyze the results of these batches to determine the profitability of your production line.

See the instructions on the "Controlling Variation" page for details on how to do this.

Your goal is make 8 batches of 10 pills each, and see if you can consistently turn a high profit.

Here is your cost schedule.

Income

Action	Income
Income per pill successfully made (marble completes the maze)	\$100 / pill

Expenses

Action	Expense
Cost to develop & build maze	\$1500 / factory
Minor design change (tighten or adjust a piece)	\$50 / piece
Redesign (move a piece to a different location)	\$100 / piece

Controlling Variation

The purpose of this exercise is to illustrate the difference between **tampering** and **controlling variation**.

1. Identify Your Roles : Builder(s), Analyst(s), Observer(s), and Recorder

2. Builders – Build Production Line

- Production line = marble maze
- Must use all enclosed parts
- Cannot use any parts not included in the set

3. Analysts & Observers – Make Pills

- Make 1 batch of 10 pills (let 10 marbles to run through maze) & record your results on the **Check Sheet**
- Observe each batch carefully, identifying any problems areas in the production line (e.g., marbles jumping out of the maze, getting stuck, not following the correct path, etc.)
- **Do not make any changes!**

4. Recorder – Record Observations

- Record the number of pills in the batch that were properly made (finished maze in the appropriate place) on the **Check Sheet**
- Record any areas of difficulty with the production line (maze/marbles) under **Observations / Analysis**

5. Entire Team – Analyze the Observations

- Identify the problem spots
- Determine what production line changes to make & record your changes under **Observations / Analysis**
- Make the changes to the maze

6. Make Another Batch of Pills

- Repeat steps 3-5

7. Make More Batches of Pills

- Decide which strategy your team will use (combinations OK) and note on **Check Sheet** under **Strategy**:
 - Managing Variation – Repeat steps 3-5 without changes or adjustments
 - Minor design changes / tightening & tweaking – Make 1 batch at a time, but tweak your line as needed after each run.
 - Redesign / moving pieces – Make 1 batch at a time, but redesign as needed after each run
- Make a total of 8 batches – if first batches were “catastrophic”, can make up to 10 batches

8. Analyze Your Batches

- Were your later batches better than your earlier ones?
- Did you manage your variation or tweak as you went.
- Write your conclusions on the **Check Sheet**.

Check Sheet

of Batches Made _____

Total Cost Incurred \$ _____

Number of pills produced successfully in each batch :

Batch #:	1	2	3	4	5	6	7	8	9	10
# Pills Produced:										

Observations & Costs associated with each Batch

Batch #	Observations / Analysis	Strategy	Income	Expenses	Balance
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Conclusions

Mosaic Activity – Preparation:

Kit Preparation:

1. Number kits M001 through M030
2. For the 3 different kit types (see table below)
 - open packages of mosaic pieces
 - count out the appropriate number of pieces of each color
 - place counted pieces in separate ziplock bags, 1 bag for each color
 - place all spare pieces in a fifth ziplock bag, label bag with kit number,

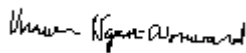
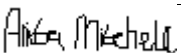
Kit Numbers	Kit Type	Orange pieces	Purple pieces	Turquoise pieces	Yellow pieces
M001 through M015	Face	7	16	24	25
M016 through M020	Yellow to Orange Face	25	16	24	7
M021 through M030	Target not Face	10	24	18	20

Scenario Preparation for MESA Day:

1. Print out SOP and batch record pairs:
 - Mosaic SOP / Mosaic Batch Record : 15 copies
 - Mosaic SOP YtoOface / Mosaic Batch Record YtoOface : 10 copies
 - Mosaic SOP targetnotface / Mosaic Batch Record targetnotface : 5 copies
2. Assemble the 30 scenarios according to the table below

Scenario	Number of this scenario	Kit Numbers	SOP version	Batch Record version
Face Mosaic	15	M001 – M015	Mosaic SOP	Mosaic Batch Record
Yellow to Orange Face Mosaic	5	M016 – M020	MosaicSOP YtoOface	Mosaic Batch Record YtoOface
Target Mosaic	5	M021 – M025	Mosaic SOP targetnotface	Mosaic Batch Record targetnotface
Not able to make mosaic	5	M026 – M030	MosaicSOP YtoOface	Mosaic Batch Record YtoOface

BATCH RECORD – 1234 : Mosaic Design Assembly

Approvals:	Name	Date	Signature
Author	Vivian Ngan-Winward	2010-11-09	
Reviewer	Anita Mitchell	2010-11-09	

Document History:

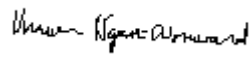
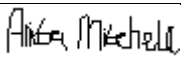
Revision Number	Date	Purpose	Effector
1	2010-11-15	Initial release	Vivian Ngan-Winward

Assembly:

Mosaic Mysteries kit number :			
Material Inventory:	Amount Needed	Amount Available	Initials of Worker Checking
Display tray	1		
Orange mosaic pieces	7		
Purple mosaic pieces	16		
Turquoise mosaic pieces	24		
Yellow mosaic pieces	25		
Comments :	Worker Name(s) [print]		Initials
Batch ID number :		Date :	

Work Review	Supervisor Name (print)	Supervisor Signature	Date

SOP – 1234 : Assembly of the Mosaic Design

Approvals:	Name	Date	Signature
Author	Vivian Ngan-Winward	2010-11-09	
Reviewer	Anita Mitchell	2010-11-09	

Document History:

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1. Purpose:

- 1.1. To assemble the mosaic design.

2. Scope:

- 2.1. This procedure should be followed to assemble the mosaic design using the Mosaic Mysteries kit.

3. Responsibilities:

- 3.1. Workers using this procedure must be adequately trained to perform this procedure.
- 3.2. Workers using this procedure are responsible for following the facility's safety procedures.
- 3.3. Workers using this procedure are responsible for following proper documentation policies.

4. References:

- 4.1. SOP-1111 *Facility Rules and Regulations*
- 4.2. SOP-2222 *Proper Documentation Procedures*
- 4.3. BR-1234 *Mosaic Design Assembly*

5. Definitions:

- 5.1. “**Mosaic piece**” means any of the colored trapezoidal plastic pieces in the Mosaic Mysteries kit.

6. Precautions:

- 6.1. Take care not to lose any mosaic pieces from the kit.
- 6.2. Assembly should be performed on a level work surface.

7. Equipment and Materials:

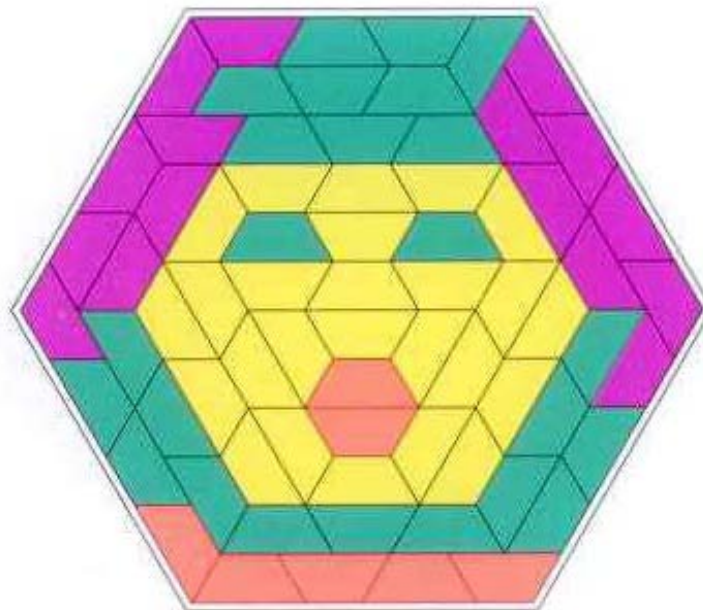
- 7.1. Mosaic display tray: 1
- 7.2. Orange mosaic pieces: 7
- 7.3. Purple mosaic pieces: 16

SOP – 1234 : Assembly of the Mosaic Design

- 7.4. Turquoise mosaic pieces: 24
- 7.5. Yellow mosaic pieces: 25
- 7.6. Work surface

8. Procedure:

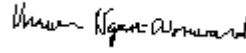
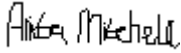
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- 8.3. Take inventory of the materials in your Mosaic Mysteries kit and complete the material inventory in *Assembly* section of the batch record.
- 8.4. Using the follow mosaic pattern as a guide, assemble the mosaic design by placing the mosaic pieces in the display tray. When placing the mosaic pieces, start from the edge and work toward the center of the design.



- 8.5. When assembly is complete, report to your supervisor and obtain from him/her the *Batch ID* number. Complete the remaining parts of the *Assembly* section in the batch record. Your supervisor should complete the *Work Review* section of the batch record.

9. Attachments: n/a

BATCH RECORD – 1234 : Mosaic Design Assembly

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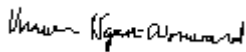
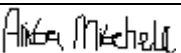
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Assembly:

Mosaic Mysteries kit number :			
Material Inventory:	Amount Needed	Amount Available	Initials of Worker Checking
Display tray	1		
Orange mosaic pieces	10		
Purple mosaic pieces	24		
Turquoise mosaic pieces	18		
Yellow mosaic pieces	20		
Comments :	Worker Name(s) [print]		Initials
Batch ID number :		Date :	

Work Review	Supervisor Name (print)	Supervisor Signature	Date

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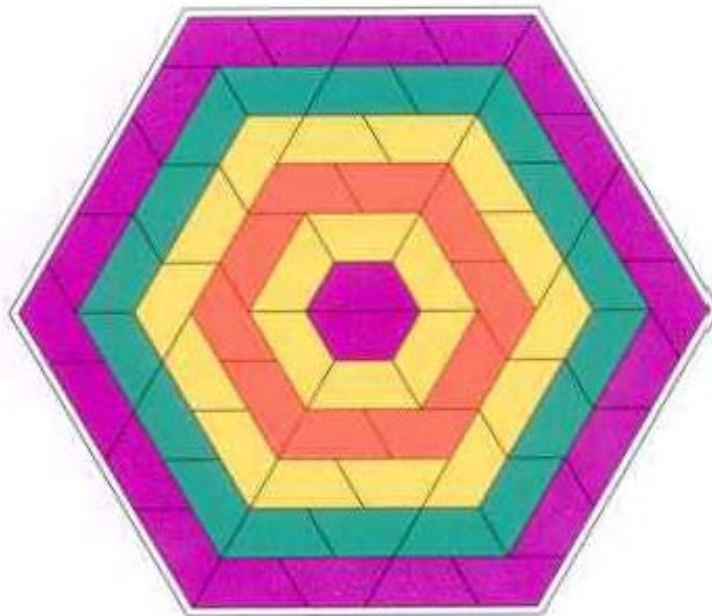
- 7.1. Mosaic display tray: 1
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- 7.3. Purple mosaic pieces: 24

SOP – 1234 : Assembly of the Mosaic Design

- 7.4. Turquoise mosaic pieces: 18
- 7.5. Yellow mosaic pieces: 20
- 7.6. Work surface

8. Procedure:

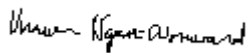
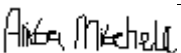
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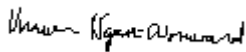
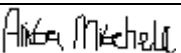
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Assembly:

Mosaic Mysteries kit number :			
Material Inventory:	Amount Needed	Amount Available	Initials of Worker Checking
Display tray	1		
Orange mosaic pieces	25		
Purple mosaic pieces	16		
Turquoise mosaic pieces	24		
Yellow mosaic pieces	7		
Comments :	Worker Name(s) [print]		Initials
Batch ID number :		Date :	

Work Review	Supervisor Name (print)	Supervisor Signature	Date

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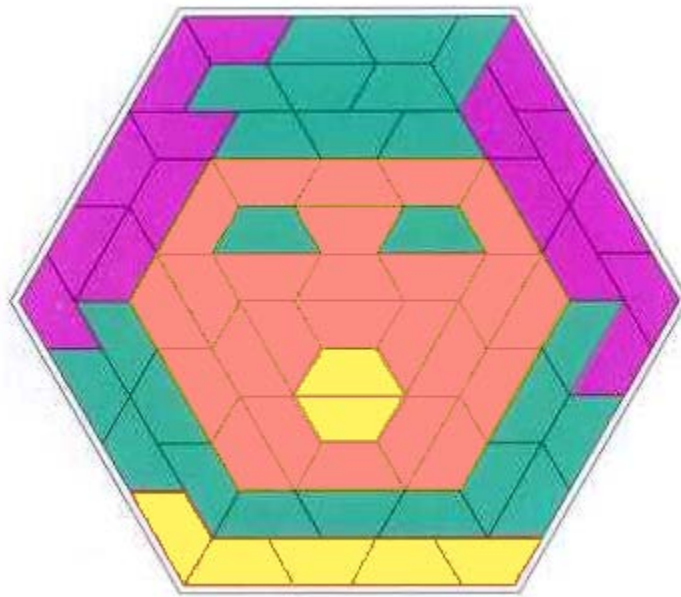
- 7.1. Mosaic display tray: 1
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SOP – 1234 : Assembly of the Mosaic Design

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- 7.6. Work surface

8. Procedure:

- 8.1. Use this SOP in conjunction with BATCH RECORD-1234 *Mosaic Design Assembly*. Record the lot number for each one of the materials used. Complete the batch record as directed.
- 8.2. Before beginning, make sure your work area is clean. If needed, wipe area with damp paper towel and discard towel.
- 8.3. Take inventory of the materials in your Mosaic Mysteries kit and complete the material inventory in *Assembly* section of the batch record.
- 8.4. Using the follow mosaic pattern as a guide, assemble the mosaic design by placing the mosaic pieces in the display tray. When placing the mosaic pieces, start from the edge and work toward the center of the design.



- 8.5. When assembly is complete, report to your supervisor and obtain from him/her the *Batch ID* number. Complete the remaining parts of the *Assembly* section in the batch record. Your supervisor should complete the *Work Review* section of the batch record.

9. Attachments: n/a