ISO 9001:2000 and making cookies

How does ISO 9001:2000 apply to a business? Let's say you make cookies…

First, the standard doesn't consider the actual quality of the cookie, you and your customers do. Whether it's chocolate chip, sugar cookie, or garbage flavor, the market (customers) will ultimately decide if your cookie is good. The standard tries to get you to achieve consistent results and continually improve the process. Thus, if you can make a good cookie ***most*** of the time, this helps you make it **all** of the time.

Quality Policy – To randomly sample our product to ensure consistency to design
Quality Objectives - Every cookie will be soft and chewy, safe to eat, etc.

Let's look at this common recipe for making cookies and apply parts of the standard to it.
Ingredients:

- **2 1/4 cups all-purpose flour**
- **1 teaspoon baking soda**
- **1 teaspoon salt**
- **1 cup (2 sticks) butter, softened**
- **3/4 cup granulated sugar**
- **3/4 cup packed brown sugar**
- **1 teaspoon vanilla extract**
- **2 large eggs**
- **2 cups (12-oz. pkg.) Semi-Sweet Chocolate Morsels**

PREHEAT oven to 375° F.
COMBINE flour, baking soda and salt in small bowl.
BEAT butter, granulated sugar, brown sugar and vanilla extract in large mixer bowl ***until creamy.***
Add eggs, one at a time, beating well after each addition.
Gradually beat in flour mixture.
Stir in morsels.
DROP by rounded tablespoon onto ungreased baking sheets.

BAKE for 9 to 11 minutes or until golden brown.
Cool on baking sheets for 2 minutes;

- remove to wire racks to cool completely.

Let's break down the (oversimplified) process of making cookies into the sections of the standard:

ISO 9001:2000 Standard applied to cookies

Section 1: Scope
Talks about the standard and how it applies to organizations

Section 2: Normative Reference
References another document that should be used along with the standard, ISO 9000:2000, Quality Management Systems-Fundamentals and Vocabulary

Section 3: Terms and Definitions
Gives a few new definitions

Section 4: General Requirements
Gives requirements for the overall Quality Management System
4.1 Identify all your processes:

- Purchase materials – (includes selecting vendors that meet product spec's)
- Receive/inspect materials
- Store Materials
- Measure Ingredients (take out of storage)
- Beat/Stir, etc.
- Drop onto cookie sheet
- Bake
- Pack
- Ship
- Clean Kitchen

4.2 Documentation (can be in any form or medium)

- Quality Policy, Objectives, Manual, Planning forms, records

4.2.2 Quality Manual

- Scope, Procedures, Description of their interaction.

4.2.3 Control of Documents

- Create a list of the necessary documents in addition to the ones mentioned above:
  - List of vendors
  - Forms and records for recording data
  - Etc.
- Assign a numbering system so you can control these items (or use software)
- Ensure that updates are approved as specified

4.2.4 Control of Records – keep them in one place as evidence of conformity

Section 5: Management Responsibility
Gives requirements for Management and their role in the Quality Management System
5.2 Customer Focus

- Management should ensure you are meeting customer requirements.

5.6 Management Review

- Review of the QMS to make sure it is meeting it's stated objectives.

5.6.2 Review Input

- Results of audits, customer feedback, CAPA status, etc.

5.6.3 Review Output

- Improvement in the processes, meeting of customer requirements, and resource needs

Section 6: Resource Management

Gives requirements for resources including personnel, training, the facility and work environment

6.1 The organization will have the resources needed to carry out the objectives

- Do you have enough money to perform testing, hire auditors, etc?

6.2 Human Resources

6.2.2 Competence, Awareness and Training

- Have the people been trained on the equipment? (ovens, mixers, etc.)
- Was the training effective? (measure performance)
- Maintain records, etc.

6.3 Infrastructure

Have you created the right environment to produce to customer specifications?

- Do you have the tools to remove the cookies from oven before they burn?
- Etc.

6.4 Work Environment

- Do you control the humidity in the bakery?

Section 7: Product Realization

Gives requirements for the production of the product or service, including things like planning, customer related processes, design, purchasing and process control

7.1 Planning of product realization – relates back to processed identified in Sec. 4.1

- Quality Objectives for the Product – are the cookies to be soft or crispy?
- Resources – baking instructions, mixing instructions, etc.
- Verification, validation, monitoring, inspection and test for product acceptance
    - Are we buying the correct ingredients and do they meet our specs?
    - Are ingredients being measured correctly?
    - Is batter “creamy” when mixing as design requires?
    - Are eggs added one at a time?
    - Are the cookies formed into rounded balls?
    - Is cookie sheet ungreased?
    - Taste Testing?
- Record as evidence to ensure you’re meeting objectives

7.2 Customer-related processes

7.2.1 Determine requirements for the customer

- Are the cookies chewy?
- Are they clean from bacteria?
- Is the packaging sealed?

7.2.2 Review of requirements related to product

- Are the requirements defined? (how/when/where does the customer want their cookies?)
- Do they want the Pan Cookie variation? If so, this requires different processes, etc.
- Can we meet these expectations? (conducted prior to order acceptance)
    - Do we have time to make them as requested?
    - Do we have the ingredients? Etc.

7.3.1 Design and development planning

7.3.2 Design and development inputs

- Functional requirements: Size, shape, flavor
- Statutory requirements: FDA guidelines, etc.

Section 7: Product Realization (cont'd)

7.3.3 Design and development outputs
- Specify the characteristics of the product so they may be verified along the way.
- What is creamy? Are they the right size? Are they baked long enough for food safety? Etc.

7.3.4 Design and development review
- Perform reviews to ensure the process is working as expected

7.4.1 Purchasing process
- Make sure that purchased product conforms to the spec's:
- Evaluate suppliers – do the eggs arrive unbroken? Etc.

7.4.2 Purchasing information
- Purchasing info describes the product – type of ingredients, specifications, etc.
- Some examples may be: Type of flour, light or dark chocolate morsels, etc.

7.4.3 Verification of purchased product
- Inspecting the ingredients to make sure they are right.

7.5.1 Control of production and service provision
- Is the recipe accessible to all parties involved?
- Are work instructions available? (how to measure, beat, etc.)
- Is the oven temperature clearly visible?

7.5.2 Validation of Processes…
If you can't test the product, then validate the process. A good example of using this is ammunition. You can't test or evaluate the ability of the product to meet specifications without completely destroying the bullet. Since cookies are a batch process, you can sample some of the batch. This clause won't be needed for cookies.

7.5.3 Identification and Traceability
- How do you identify each batch of cookies throughout production?

7.5.4 Customer Property
- If a customer supplies nuts for their order, they need to be identified, safeguarded, etc.

7.5.5 Preservation of product
- How do you store batter until it is ready to be baked?
- Where do you put finished cookies to keep them fresh?

7.6 Control of monitoring and measuring devices
- How do you ensure the oven thermometer is working correctly? Calibrate it.
- Keep records

Section 8: Measurement, Analysis and Improvement

Gives requirements on monitoring processes and improving those processes

8.2.1 Customer satisfaction
- How do you ensure you are meeting customer requirements? Are you getting rejects returned from the customer? Does the customer require new flavors? Etc.

8.2.2 Internal Audit
- Audit your processes to ensure conformity on a regular basis.
- Basically: make sure people are following the recipe without deviation.
- Keep records.

8.2.3 Monitoring and measurement of processes
- Make sure the cookies meet your satisfaction. Are they burned?
- Do some cookies have too much chocolate and others not enough?
- Keep records

8.3 Control of non-conforming product
- Can they be salvaged?
- Keep the bad ones from being sent to customers!
- Keep records

8.4 Analysis of data
- Rate your cookies – are they being made consistently?
- Do they meet the stated objectives?

8.5.1 Continuous improvement
- How can you make the cookies better, more consistent, etc.
- Look for ways: higher temperature for less time in the oven?
- Look at each process for improvement opportunities

8.5.2 Corrective action
- Fix your mistakes. Are the cookies to crisp? Are they too small? Whatever it is, you need to determine which process needs improvement.

8.53 Preventive action
- What can be done to ensure mistakes don't happen?
- How do you ensure egg shells don't get in the batter? Etc.