

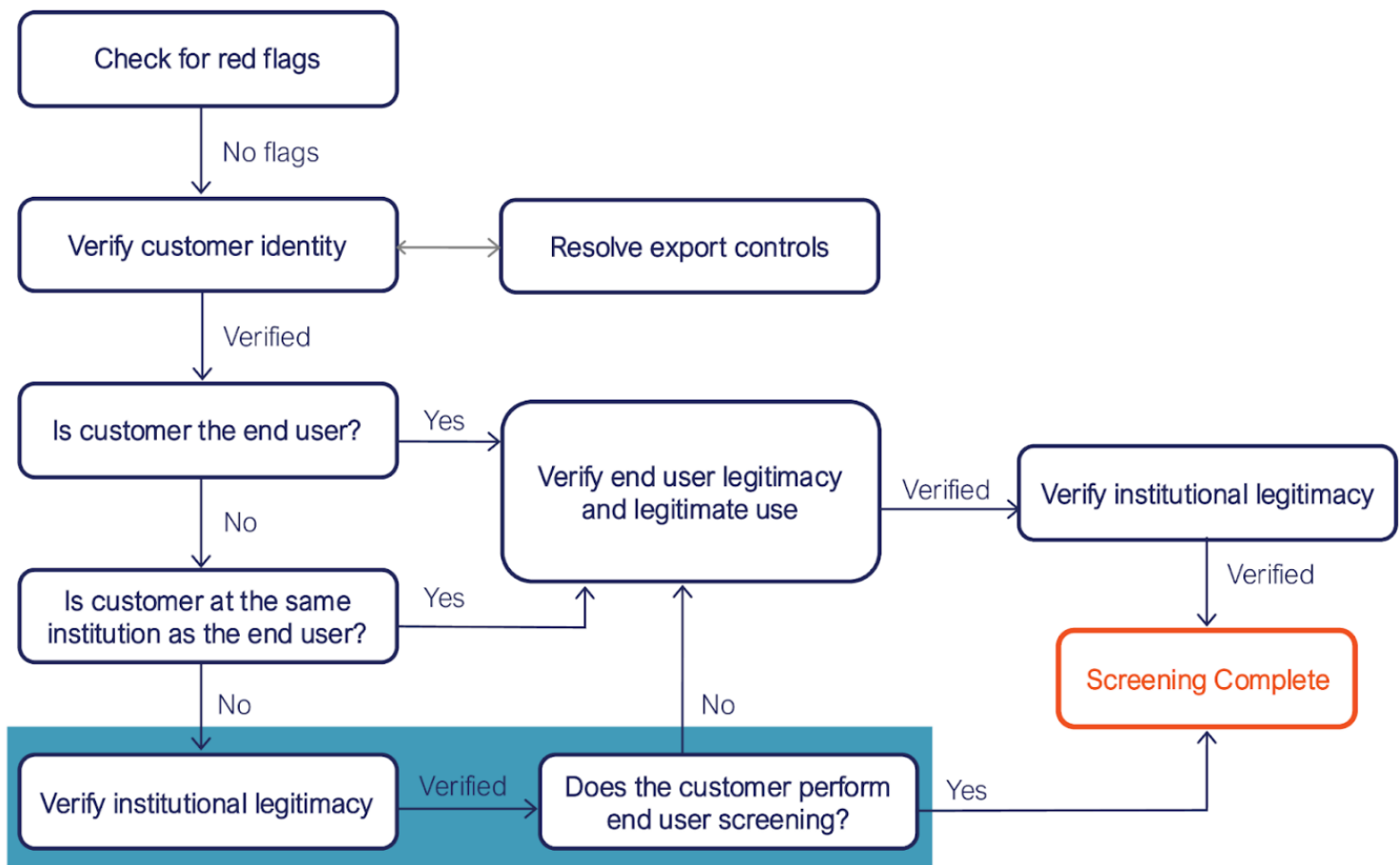
SOC ORDER FORM | SCREENING DECISION GUIDE

SOC ORDER FORM

This guide outlines **steps for screening customers** using the SOC Order Form. It helps providers of synthetic nucleic acids, such as companies, core facilities, and biofoundries, verify that customers have **legitimate use** and **appropriate biorisk management** when ordering nucleic acid sequences of concern (SOCs).

Due diligence for customer screening depends on both the order and the customer. Some SOCs have legitimate uses that require few precautions. For SOCs that pose significant biosafety or biosecurity risks, providers should establish a **high level of confidence** in the customer's identity, legitimacy, and institutional oversight. While this guide suggests one approach to conducting appropriate due diligence, each provider remains responsible for their own customer acceptance decisions.

OVERVIEW



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STEP-BY-STEP INSTRUCTIONS

For orders containing sequences of concern (SOCs) that may pose a biosafety or biosecurity risk, such as those that match agents regulated by policies like export controls, the UK Guidance, or the US Framework, or that contribute to pathogenicity, virulence, or toxicity, request that the customer fill out a SOC Order Form.

1. Check for red flags

Refer to Questions 1.1 and 1.2 in Part 1, as well as the customers' New Customer Form.

Red flags indicate that the order may be intended for an inappropriate end-use, customer, or destination.

Verification step: Check for Red Flags	Outcome
Check that customer details, including institution and shipping address, are consistent with information from previous orders or from the New Customer Form.	
<p>Check if the customer has made any unusual requests, which could include:</p> <ul style="list-style-type: none">- Labeling or shipping procedures (e.g. requests to misidentify the goods on the packaging, requests to change the recipient's name after the order is placed, but before it is shipped).- Method of payment (e.g., arranging payment in cash, through a non-bank third party, or cryptocurrency) or offering to pay using unusually favorable payment terms, such as a higher-than-expected price- Confidentiality conditions, particularly with respect to the final destination or the destruction of transaction records.- Reagents or materials for synthesis (mirror nucleic acids, non-canonical amino acids, reconfiguring standard reagents) <p>If found, reject the customer OR request more information to verify their identity and to establish why these requests are necessary.</p>	
Check that the ordered sequence is an SOC, consistent with Question 1.2.	

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2. Verify customer identity with enhanced due diligence

Refer to Question 1.1 in Part 1: Customer Information

In each box below, you will find verification steps that can help establish customer identity, listed in order from lower to higher levels of due diligence. Not all steps are necessary for all orders. SOC's that pose higher levels of biosafety or biosecurity risk require higher levels of confidence in the customer's identity.

<i>Verification step: Customer Identity</i>	<i>Outcome</i>
<p>Verify individual identity</p> <ol style="list-style-type: none"> 1) <i>(lower confidence)</i> Verify the email address and phone number (for example, by sending a code that is reported back). 2) Call the customer, conduct a video conference, or otherwise establish real-time contact to verify identity. 3) Verify identification using an established third-party service (e.g. Veriff, Plaid, CLEAR, Persona, or DigiLocker). 4) <i>(higher confidence)</i> Request a copy of a government-issued ID or other identifying documents. 	
<p>Check that the shipping address is consistent with institution</p> <ol style="list-style-type: none"> 1) <i>(lower confidence)</i> Check that the address is in the expected geographic location and is consistent with information from the website. 2) Check that the address is consistent with the address given by other customers at the same institution. 3) Use a mapping platform (e.g., Google Maps) to determine that the address is unlikely to be residential. 4) <i>(higher confidence)</i> Use a mapping platform or other public data to verify that there is a legitimate biomedical business or research institution at the location. 	
<p>Check institutional affiliation</p> <p><i>If the customer is not affiliated with an institution or if the email address or shipping address do not match the institution, check that the customer has a reasonable explanation.</i></p>	

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3. Resolve export control needs

Refer to Question 1.3 in Part 1: Order Information

<i>Verification step: Export Control</i>	<i>Outcome</i>
If the order requires an export license, and the customer does not have one or is unsure, work with the customer to obtain the license.	

4. Is the customer the end user?

Refer to Questions 1.4, 1.5 and 1.6 in Part 1: Customer Information

<i>Verification step: Relationship between Customer and End User</i>	<i>Outcome</i>
If the customer is the end user (answered "Yes" to Question 1.4): → Check customer completed <i>Part 2</i> and <i>Part 3</i> .	<i>Continue verification</i>
If the customer and the end user are at the same institution (per Question 1.5): → Check end user completed <i>Part 2</i> and <i>Part 3</i> .	<i>Continue verification</i>
If external distribution without screening (answered "No" to Question 1.6) → Check end user completed <i>Part 2</i> and <i>Part 3</i> .	<i>Continue verification</i>
If external distribution with screening (answered "Yes" to Question 1.6): 1) Verify institutional legitimacy with <u>enhanced due diligence</u> . Refer to documentation provided on the New Customer Form to establish institutional legitimacy and request additional documentation, if needed, to gain confidence. 2) If the institution is legitimate and the customer conducts biosecurity screening, then screening is complete.	

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5. Verify end user legitimacy and legitimate use

This section should establish that the end user is a legitimate member of the life sciences community with a legitimate reason to use the SOC's ordered. SOC's that pose higher levels of biosafety or biosecurity risk require higher levels of confidence that the end user has a legitimate use.

Refer to Questions 2.1 and 2.2 in Part 2: Legitimate Use

Verification step: Legitimate Use	Outcome
Check institutional affiliation <i>If the end user is not affiliated with an institution or if the email address or shipping address do not match the institution, check that the customer has a reasonable explanation.</i>	
Check intended use <i>Check that the use described in Question 2.2 is reasonable for the SOC's ordered.</i>	

Refer to Question 2.3 in Part 2: Legitimate Use

Verification step: Individual Legitimacy	Outcome
Verify that the end user is a legitimate member of the scientific community. For example, check that: <ul style="list-style-type: none">- Documentation is recent or current (e.g., expected dates included in funding documentation, papers published in the last year, current profile on institutional website).- User's scientific record is consistent with their intended use.- Documentation is consistent with the user's institutional affiliation.	

Refer to Signature line in Part 2: Legitimate Use

Verification step: Signature	Outcome
Verify that Part 2 is signed and dated less than one year ago.	

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6. Verify biorisk management

This section should establish that the end user has appropriate biorisk management for the SOC's ordered.

SOCs that pose higher levels of biosafety or biosecurity risk require higher levels of confidence that the institution is legitimate and provides sufficient biosafety and biosecurity oversight. For work with high-risk SOC's (e.g. large portions of viral genomes), Section 3A should be required. Section 3B should only be used if a product does not pose a significant biosafety or biosecurity risk.

Refer to Part 3: Biorisk Management

Verification step: Intended End Use	Outcome
Check that End User name, institution, and project description match those in Parts 1 and 2 of the form.	

Refer to Part 3A: Institutional Approval of Biorisk Management

Verification step: Institutional Approval	Outcome
If the institution is unfamiliar or not well-established, verify the legitimacy of the institution by requesting additional documentation from the end user. Types of documentation of legitimacy are listed in Section 3B .	
Verify institutional contact provided in Section 3A.1 . For example: 1) (<i>lower confidence</i>) Check that the email address, phone number, and/or website is associated with the institution. If contact information does not match the expected institution, check that the explanation provided is reasonable. 2) Use a search engine to determine that the individual listed is associated with the institution or contact the customer to clarify. 3) Verify the email address and phone number (for example, by sending a code that is reported back) 4) (<i>higher confidence</i>) Call the contact, conduct a video conference, or otherwise establish real-time contact to verify identity.	

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Check that the biosafety and biosecurity practices indicated in Section 3A.2 are reasonable for the ordered products. If the ordered products fall under regulatory control, ensure that regulatory approvals are included in the oversight.	
Check that the form is signed in Section 3A.3 and that the date is within one year of the date of the order.	
If the information is verified and the form is signed, then no additional checks are needed. Screening is complete.	<i>Screening complete</i>

Refer to Question 3B.1 in Section 3B: Other Documentation of Biorisk Management

<i>Verification step: Verify documentation with <u>enhanced due diligence</u></i>	<i>Outcome</i>
Check the documentation with <u>enhanced due diligence</u> to ensure that the institution or company is legitimate, for example, by verifying documentation for at least two of the standards (checkboxes) provided on the form.	

Refer to Question 3B.2 in Section 3B: Other Documentation of Biorisk Management

<i>Verification step: Establishing biorisk oversight without institutional approval</i>	<i>Outcome</i>
<p>Check that the biorisk management practices and explanation provide a reason to believe:</p> <ul style="list-style-type: none"> - The products can be used safely without institutional biosafety oversight. - If the product falls under regulatory control, that the end user and institution have the appropriate permits or registrations - The end user has a legitimate use for the products. - The project is legitimate even though it does not have an individual who can provide the authorization. 	
If the explanation is reasonable and the ordered products do not pose a significant biosafety or biosecurity risk, then no additional checks are needed. Screening is complete.	<i>Screening complete</i>